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**Title 42 - Public Health****Chapter I - Public Health Service, Department of Health and Human Services****Subchapter D - Grants****Part 50 - Policies of General Applicability****ENHANCED CONTENT - TABLE OF CONTENTS****Subpart D Public Health Service Grant Appeals Procedure 50.401 – 50.406****§ 50.401** What is the purpose of this subpart?**§ 50.402** To what program do these regulations apply?**§ 50.403** What is the policy basis for these procedures?**§ 50.404** What disputes are covered by these procedures?**§ 50.405** What is the structure of review committees?**§ 50.406** What are the steps in the process?**◉ Subpart D - Public Health Service Grant Appeals Procedure****Authority:** Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); 45 CFR 16.3(c).**Source:** 54 FR 34770, Aug. 22, 1989, unless otherwise noted.**◉ § 50.401 What is the purpose of this subpart?**

This subpart establishes an informal procedure for the resolution of certain postaward grant and cooperative agreement disputes within the agencies and offices identified in § 50.402.

*[63 FR 66062, Dec. 1, 1998]*

**◉ § 50.402 To what program do these regulations apply?**

This subpart applies to all grant and cooperative agreement programs, except block grants, which are administered by the National Institutes of Health; The Centers for Disease Control and Prevention; the Agency for Toxic Substances and Disease Registry; the Food and Drug Administration; and the Office of Public Health and Science. For purposes of this subpart, these entities are hereinafter referred to as “agencies.”

*[70 FR 76175, Dec. 23, 2005]*

**◉ § 50.403 What is the policy basis for these procedures?**

The Secretary of Health and Human Services has established a Departmental Appeals Board for the purpose of providing a fair and flexible process for the appeal of written final decisions involving certain grant and cooperative agreement programs administered by constituent agencies of the Department. The regulatory provision which establishes the circumstances under which the Board will accept an appeal (45 CFR 16.3)

provides, among other things, that the appellant must have exhausted any preliminary appeal process required by regulation before a formal appeal to the Departmental Board will be allowed. This subpart provides such an informal preliminary procedure for resolution of disputes in order to preclude submission of cases to the Departmental Appeals Board before an agency identified in § 50.402 has had an opportunity to review decisions of its officials and to settle disputes with grantees.

*[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]*

#### ◉ § 50.404 What disputes are covered by these procedures?

- (a) These procedures are applicable to the following adverse determinations under discretionary project grants and cooperative agreements (both referred to in this subpart as grants) issued by the agencies identified at § 50.402;
  - (1) Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
  - (2) A determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.
  - (3) A determination that a grant is void.
  - (4) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.
- (b) A determination subject to this subpart may not be reviewed by the review committee described in § 50.405 unless an officer or employee of the agency has notified the grantee in writing of the adverse determination. The notification must set forth the reasons for the determination in sufficient detail to enable the grantee to respond and must inform the grantee of the opportunity for review under this subpart.

*[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]*

#### ◉ § 50.405 What is the structure of review committees?

The head of the agency, or his or her designee, shall appoint review committees to review adverse determinations made by officials for programs under their jurisdiction. A minimum of three employees shall be appointed (one of whom shall be designated as chairperson) either on an ad hoc, case-by-case basis, or as regular members of review committees for such terms as may be designated. None of the members of the review committee reviewing any given appeal may be from the office of the responsible official whose adverse determination is being appealed (e.g., project officer, grants specialist, program manager, grants management officer).

*[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66062, Dec. 1, 1998]*

#### ◉ § 50.406 What are the steps in the process?

- (a) A grantee with respect to whom an adverse determination described in § 50.404(a) above has been made and who desires a review of that determination must submit a request for such review to the head of the appropriate agency or his or her designee no later than 30 days after the written notification of the determination is received, except that if the grantee shows good cause why an extension of time should be granted, the head of the appropriate agency or his or her designee may grant an extension of time.
- (b) The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the grantee's position with respect to such issue(s) and the pertinent facts and reasons in support of the grantee's position. In addition to the required written statement, the grantee shall provide copies of any documents supporting its claim.
- (c) When a request for review has been filed under this subpart with respect to an adverse determination, no action may be taken by the awarding agency pursuant to such determination until the request has been disposed of, except that the filing of the request shall not affect any authority which the agency may have to suspend assistance or otherwise to withhold or defer payments under the grant during proceedings under this subpart. This paragraph does not require the awarding agency to provide continuation funding during the appeal process to a grantee whose noncompeting continuation award has been denied.
- (d) Upon receipt of a request for review, the head of the agency or his or her designee will make a decision as to whether the dispute is reviewable under this subpart and will promptly notify the grantee and the office responsible for the adverse determination of this decision. If the head of the agency or his or her designee determines that the dispute is reviewable, he or she will forward the matter to the review committee appointed under § 50.405.
- (e) The agency involved will provide the review committee appointed under § 50.405 with copies of all relevant background materials (including applications(s), award(s), summary statement(s), and correspondence) and any additional pertinent information available. These materials must be tabbed and organized chronologically and accompanied by an indexed list identifying each document.
- (f) The grantee shall be given an opportunity to provide the review committee with additional statements and documentation not provided in the request for review described in paragraph (b) of this section. This additional submission, which must be organized and indexed as indicated under paragraph (e) of this section, should provide only material that is relevant to the review committee's deliberation of the issues in the case.
- (g) The review committee may, at its discretion, invite the grantee and/or the agency staff to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.
- (h) Based on its review, the review committee will prepare a written decision to be signed by the chairperson and each of the other committee members. The review committee shall send the written decision with a transmittal letter to the grantee and shall send a copy of both to the official responsible for the adverse determination. If the decision is adverse to the grantee's position, the transmittal letter must state the grantee's right to appeal to the Departmental Appeals Board under 45 CFR part 16.

*[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66063, Dec. 1, 1998]*

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## **Title 42 - Public Health**

### **Chapter I - Public Health Service, Department of Health and Human Services**

#### **Subchapter D - Grants**

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## ◎ PART 59 - GRANTS FOR FAMILY PLANNING SERVICES

### ◎ Subpart A - Project Grants for Family Planning Services

**Source:** 86 FR 56177, Oct. 7, 2021, unless otherwise noted.

#### ◎ § 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

#### ◎ § 59.2 Definitions.

As used in this subpart:

**Act** means the Public Health Service Act, as amended.

**Adolescent-friendly health services** are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

**Clinical services provider** includes physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.

**Client-centered care** is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.

**Culturally and linguistically appropriate services** are respectful of and responsive to the health beliefs, practices and needs of diverse patients.

**Family** means a social unit composed of one person, or two or more persons living together, as a household.

**Family planning services** include a broad range of medically approved services, which includes Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

**Health equity** is when all persons have the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

**Inclusive** is when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders

and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

**Low-income family** means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

**Nonprofit**, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

**Quality healthcare** is safe, effective, client-centered, timely, efficient, and equitable.

**Secretary** means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

**Service site** is a clinic or other location where Title X services are provided to clients. Title X recipients and/or their subrecipients may have service sites.

**State** includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, et al.), the Marshall Islands, the Federated State of Micronesia, and the Republic of Palau.

**Trauma-informed** means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.

### § 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

### § 59.4 How does one apply for a family planning services grant?

- (a) Application for a grant under this subpart shall be made on an authorized form.
- (b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.
- (c) The application shall contain
  - (1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;
  - (2) A budget and justification of the amount of grant funds requested;
  - (3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

- (4) Such other pertinent information as the Secretary may require.

⦿ **§ 59.5 What requirements must be met by a family planning project?**

- (a) Each project supported under this part must:

- (1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested.
- (2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.<sup>[1]</sup>
- (3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.
- (4) Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.
- (5) Not provide abortion as a method of family planning.<sup>[2]</sup> A project must:
  - (i) Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:
    - (A) Prenatal care and delivery;
    - (B) Infant care, foster care, or adoption; and
    - (C) Pregnancy termination.
  - (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and, referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.
- (6) Provide that priority in the provision of services will be given to clients from low-income families.
- (7) Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(i) Family income should be assessed before determining whether copayments or additional fees are charged.

(ii) With regard to insured clients, clients whose family income is at or below 250 percent of the FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

(9) Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.

(10) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required.

(11)

(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for opportunities for community education, participation, and engagement to:

- (i) Achieve community understanding of the objectives of the program;
  - (ii) Inform the community of the availability of services; and
  - (iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.
- (4) Provide for orientation and in-service training for all project personnel.
  - (5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.
  - (6) Provide that family planning medical services will be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.
  - (7) Provide that all services purchased for project participants will be authorized by the project director or their designee on the project staff.
  - (8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.
  - (9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary.
  - (10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

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**FOOTNOTES - 59.5**

<sup>[1]</sup> 42 U.S.C. 300a-8 provides that any officer or employee of the United States, officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.

<sup>[2]</sup> Providers may separately be covered by federal statutes protecting conscience and/or civil rights.

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⦿ **§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?**

- (a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.
- (b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:
  - (1) **Size.** The committee shall consist of no fewer than five members and up to as many members the recipient determines, except that this provision may be waived by the Secretary for good cause shown.
  - (2) **Composition.** The committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).
  - (3) **Function.** In reviewing materials, the Advisory Committee shall:
    - (i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;
    - (ii) Consider the standards of the population or community to be served with respect to such materials;
    - (iii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;
    - (iv) Determine whether the material is suitable for the population or community to which is to be made available; and
    - (v) Establish a written record of its determinations.

● **§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?**

- (a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:
  - (1) The number of clients, and, in particular, the number of low-income clients to be served;
  - (2) The extent to which family planning services are needed locally;
  - (3) The ability of the applicant to advance health equity;
  - (4) The relative need of the applicant;

- (5) The capacity of the applicant to make rapid and effective use of the federal assistance;
  - (6) The adequacy of the applicant's facilities and staff;
  - (7) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and
  - (8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.
- (b) The Secretary shall determine the amount of any award on the basis of an estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.
  - (c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

⦿ **§ 59.8 How is a grant awarded?**

- (a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re compete for funds. This anticipated period will usually be for three to five years.
- (b) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.
- (c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

⦿ **§ 59.9 For what purpose may grant funds be used?**

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75.

⦿ **§ 59.10 Confidentiality.**

- (a) All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.



- (b) To the extent practical, Title X projects shall encourage family participation.<sup>[3]</sup> However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

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**FOOTNOTES - 59.10**

<sup>[3]</sup> 42 U.S.C. 300(a).

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⦿ **§ 59.11 Additional conditions.**

The Secretary may, with respect to any grant, impose additional conditions prior to, at the time of, or during any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

⦿ **Subpart B [Reserved]**

⦿ **Subpart C - Grants for Family Planning Service Training**

**Authority:** Sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-4; sec. 6(c), 84 Stat. 1507, 42 U.S.C. 300a-1.

**Source:** 37 FR 7093, Apr. 8, 1972, unless otherwise noted.

⦿ **§ 59.201 Applicability.**

The regulations in this subpart are applicable to the award of grants pursuant to section 1003 of the Public Health Service Act (42 U.S.C. 300a-1) to provide the training for personnel to carry out family planning service programs described in sections 1001 and 1002 of the Public Health Service Act (42 U.S.C. 300, 300a).

⦿ **§ 59.202 Definitions.**

As used in this subpart:

- (a) **Act** means the Public Health Service Act.
- (b) **State** means one of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Trust Territory of the Pacific Islands.
- (c) **Nonprofit** private entity means a private entity no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.
- (d) **Secretary** means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.
- (e) **Training** means job-specific skill development, the purpose of which is to promote and improve the delivery of family planning services.

⦿ **§ 59.203 Eligibility.**

- (a) **Eligible applicants.** Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart.
- (b) **Eligible projects.** Grants pursuant to section 1003 of the Act and this subpart may be made to eligible applicants for the purpose of providing programs, not to exceed three months in duration, for training family planning or other health services delivery personnel in the skills, knowledge, and attitudes necessary for the effective delivery of family planning services: *Provided, That the Secretary may in particular cases approve support of a program whose duration is longer than three months where he determines*
  - (1) that such program is consistent with the purposes of this subpart and
  - (2) that the program's objectives cannot be accomplished within three months because of the unusually complex or specialized nature of the training to be undertaken.

[37 FR 7093, Apr. 8, 1972, as amended at 40 FR 17991, Apr. 24, 1975]

⦿ **§ 59.204 Application for a grant.**

- (a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.<sup>[1]</sup> The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, and a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.
- (b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(Sec. 6(c), Public Health Service Act, 84 Stat. 1506 and 1507 (42 U.S.C. 300, 300a-1, and 300a-4))

[37 FR 7093, Apr. 8, 1972, as amended at 49 FR 38116, Sept. 27, 1984]

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**FOOTNOTES - 59.204**

<sup>[1]</sup> Applications and instructions may be obtained from the Program Director, Family Planning Services, at the Regional Office of the Department of Health and Human Services for the region in which the project is to be conducted, or the Office of Family Planning, Office of the Assistant Secretary for Health, Washington, DC 20201.

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⦿ **§ 59.205 Project requirements.**

An approvable application must contain each of the following unless the Secretary determines that the applicant has established good cause for its omission:

- (a) Assurances that:
  - (1) No portion of the Federal funds will be used to train personnel for programs where abortion is a method of family planning.

- (2) No portion of the Federal funds will be used to provide professional training to any student as part of his education in pursuit of an academic degree.
- (3) No project personnel or trainees shall on the grounds of sex, religion, or creed be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the project.
- (b) Provision of a methodology to assess the particular training (e.g., skills, attitudes, or knowledge) that prospective trainees in the area to be served need to improve their delivery of family planning services.
- (c) Provision of a methodology to define the objectives of the training program in light of the particular needs of trainees defined pursuant to paragraph (b) of this section.
- (d) Provision of a method for development of the training curriculum and any attendant training materials and resources.
- (e) Provision of a method for implementation of the needed training.
- (f) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program.
- (g) Provision of a method and criteria by which trainees will be selected.

⊙ **§ 59.206 Evaluation and grant award.**

- (a) Within the limits of funds available for such purpose, the Secretary may award grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 1003 of the Act, taking into account:
  - (1) The extent to which a training program will increase the delivery of services to people, particularly low-income groups, with a high percentage of unmet need for family planning services;
  - (2) The extent to which the training program promises to fulfill the family planning services delivery needs of the area to be served, which may include, among other things:
    - (i) Development of a capability within family planning service projects to provide pre- and in-service training to their own staffs;
    - (ii) Improvement of the family planning services delivery skills of family planning and health services personnel;
    - (iii) Improvement in the utilization and career development of paraprofessional and paramedical manpower in family planning services;
    - (iv) Expansion of family planning services, particularly in rural areas, through new or improved approaches to program planning and deployment of resources;
  - (3) The capacity of the applicant to make rapid and effective use of such assistance;
  - (4) The administrative and management capability and competence of the applicant;
  - (5) The competence of the project staff in relation to the services to be provided; and

- (6) The degree to which the project plan adequately provides for the requirements set forth in § 59.205.
- (b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:
  - (1) On the basis of his estimate of the actual indirect costs reasonably related to the project, or
  - (2) on the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.
- (c) Allowability of costs shall be in conformance with the applicable cost principles prescribed by 45 CFR part 75, subpart E.
- (d) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.
- (e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

*[37 FR 7093, Apr. 8, 1972, as amended at 38 FR 26199, Sept. 19, 1973; 81 FR 3009, Jan. 20, 2016]*

## § 59.207 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

## § 59.208 Use of project funds.

- (a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with the statute, the regulations of this subpart, the terms and conditions of the award, and, except as may otherwise be provided in this subpart, the applicable cost principles prescribed by 45 CFR part 75, subpart E.
- (b) Prior approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.
- (c) The Secretary may approve the payment of grant funds to trainees for:
  - (1) Return travel to the trainee's point of origin.
  - (2) Per diem during the training program, and during travel to and from the program, at the prevailing institutional or governmental rate, whichever is lower.

◉ **§ 59.209 Civil rights.**

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80).

◉ **§ 59.210 Inventions or discoveries.**

Any grant award pursuant to § 59.206 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

◉ **§ 59.211 Publications and copyright.**

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

◉ **§ 59.212 Grantee accountability.**

(a) **Accounting for grant award payments.** All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) [Reserved]

(c) **Accounting for grant-related income** —(1) *Interest.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or

instrumentality of a State, but does not include the governments of the political subdivisions of the State. All grantees other than a State, as defined in this subsection, must return all interest earned on grant funds to the Federal Government.

(d) **Grant closeout** —

(1) **Date of final accounting.** A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) **Final settlement.** There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (c)(1) of this section;

(iii) Any other amounts due pursuant to 45 CFR 75.307, 75.371 through 75.385, and 75.316–75.325.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

[36 FR 18465, Sept. 15, 1971, as amended at 38 FR 26199, Sept. 19, 1973; 81 FR 3009, Jan. 20, 2016]

⦿ **§ 59.213 [Reserved]**

⦿ **§ 59.214 Additional conditions.**

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

⦿ **§ 59.215 Applicability of 45 CFR part 75.**

The provisions of 45 CFR part 75, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part.

[81 FR 3009, Jan. 20, 2016]

**TITLE X - POPULATION RESEARCH AND VOLUNTARY  
FAMILY PLANNING PROGRAMS**

**PROJECT GRANTS AND CONTRACTS FOR FAMILY PLANNING SERVICES**

SEC. 1001 [300]

(a)The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). To the extent practicable, entities which receive grants or contracts under this subsection shall encourage family <sup>1</sup> participation in projects assisted under this subsection.

(b)In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c)The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d)For the purpose of making grants and contracts under this section, there are authorized to be appropriated \$30,000,000 for the fiscal year ending June 30, 1971; \$60,000,000 for the fiscal year ending June 30, 1972; \$111,500,000 for the fiscal year ending June 30, 1973, \$111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$115,000,000 for fiscal year 1976; \$115,000,000 for the fiscal year ending September 30, 1977; \$136,400,000 for the fiscal year ending September 30, 1978; \$200,000,000 for the fiscal year ending September 30, 1979; \$230,000,000 for the fiscal year ending September 30, 1980; \$264,500,000 for the fiscal year ending September 30, 1981; \$126,510,000 for the fiscal year ending September 30, 1982; \$139,200,000 for the fiscal year ending September 30, 1983; \$150,030,000 for the fiscal year ending September 30, 1984; and \$158,400,000 for the fiscal year ending September 30, 1985.

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<sup>1</sup> So in law. See section 931(b)(I) of Public Law 97-35 (95 Stat. 570). Probably should be "family".



## **FORMULA GRANTS TO STATES FOR FAMILY PLANNING SERVICES**

### **SEC. 1002 [300a]**

(a)The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b)The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c)For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d)For the purpose of making grants under this section, there are authorized to be appropriated \$10,000,000 for the fiscal year ending June 30, 1971; \$15,000,000 for the fiscal year ending June 30, 1972; and \$20,000,000 for the fiscal year ending June 30, 1973.

## **TRAINING GRANTS AND CONTRACTS; AUTHORIZATION OF APPROPRIATIONS**

### **SEC. 1003 [300a-1]**

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 1001 or 1002 of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$2,000,000 for the fiscal year ending June 30, 1971; \$3,000,000 for the fiscal year ending June 30, 1972; \$4,000,000 for the fiscal year ending June 30, 1973; \$3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; \$4,000,000 for fiscal year ending 1976; \$5,000,000 for the fiscal year ending September 30, 1977; \$3,000,000 for the fiscal year ending September 30, 1978; \$3,100,000 for the fiscal year ending September 30, 1979; \$3,600,000 for the fiscal year ending September 30, 1980; \$4,100,000 for the fiscal year ending September 30, 1981; \$2,920,000 for the fiscal year ending September 30, 1982; \$3,200,000 for the fiscal year ending September 30, 1983; \$3,500,000 for the fiscal year ending September 30, 1984; and \$3,500,000 for the fiscal year ending September 30, 1985.

## **RESEARCH**

### **SEC. 1004 [300a-2]**

The Secretary may -

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

## **INFORMATIONAL AND EDUCATIONAL MATERIALS**

### **SEC. 1005 [300a-3]**

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated \$750,000 for the fiscal year ending June 30, 1971; \$1,000,000 for the fiscal year ending June 30, 1972; \$1,250,000 for the fiscal year ending June 30, 1973; \$909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; \$2,000,000 for fiscal year 1976; \$2,500,000 for the fiscal year ending September 30, 1977; \$600,000 for the fiscal year ending September 30, 1978; \$700,000 for the fiscal year ending September 30, 1979; \$805,000 for the fiscal year ending September 30, 1980; \$926,000 for the fiscal year ending September 30, 1981; \$570,000 for the fiscal year ending September 30, 1982; \$600,000 for the fiscal year ending September 30, 1983; \$670,000 for the fiscal year ending September 30, 1984; and \$700,000 for the fiscal year ending September 30, 1985.

## **REGULATIONS AND PAYMENTS**

### **SEC. 1006 [300a-4]**

(a) Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this title shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Grants under this title shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) A grant may be made or contract entered into under section 1001 or 1002 for a family planning service project or program only upon assurances satisfactory to the Secretary that--

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in

accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.

(d)(1) A grant may be made or a contract entered into under section 1001 or 1005 only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this title and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 1001, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

### **VOLUNTARY PARTICIPATION**

SEC. 1007 [300a-5]

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this title (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

### **PROHIBITION OF ABORTION**

SEC. 1008 <sup>1</sup> [300a-6]

None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.

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<sup>1</sup> Section 1009 was repealed by section 601(a)(1)(G) of Public Law 105-362 (112 Stat. 3285).

Public Law 117–328  
117th Congress

An Act

Making consolidated appropriations for the fiscal year ending September 30, 2023,  
and for providing emergency assistance for the situation in Ukraine, and for  
other purposes.

Dec. 29, 2022  
[H.R. 2617]

*Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,*

Consolidated  
Appropriations  
Act, 2023.

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Consolidated Appropriations  
Act, 2023”.

**SEC. 2. TABLE OF CONTENTS.**

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. References.
- Sec. 4. Explanatory statement.
- Sec. 5. Statement of appropriations.
- Sec. 6. Adjustments to compensation.

**DIVISION A—AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG  
ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2023**

- Title I—Agricultural Programs
- Title II—Farm Production and Conservation Programs
- Title III—Rural Development Programs
- Title IV—Domestic Food Programs
- Title V—Foreign Assistance and Related Programs
- Title VI—Related Agency and Food and Drug Administration
- Title VII—General Provisions

**DIVISION B—COMMERCE, JUSTICE, SCIENCE, AND RELATED AGENCIES  
APPROPRIATIONS ACT, 2023**

- Title I—Department of Commerce
- Title II—Department of Justice
- Title III—Science
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- Title V—General Provisions

**DIVISION C—DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 2023**

- Title I—Military Personnel
- Title II—Operation and Maintenance
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- Title VI—Other Department of Defense Programs
- Title VII—Related Agencies
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**DIVISION D—ENERGY AND WATER DEVELOPMENT AND RELATED  
AGENCIES APPROPRIATIONS ACT, 2023**

- Title I—Corps of Engineers—Civil
- Title II—Department of the Interior
- Title III—Department of Energy

FAMILY PLANNING

For carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, \$286,479,000: *Provided*, That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

Abortions.  
Lobbying.

HRSA-WIDE ACTIVITIES AND PROGRAM SUPPORT

For carrying out title III of the Public Health Service Act and for cross-cutting activities and program support for activities funded in other appropriations included in this Act for the Health Resources and Services Administration, \$1,735,769,000, of which \$38,050,000 shall be for expenses necessary for the Office for the Advancement of Telehealth, including grants, contracts, and cooperative agreements for the advancement of telehealth activities: *Provided*, That funds made available under this heading may be used to supplement program support funding provided under the headings “Primary Health Care”, “Health Workforce”, “Maternal and Child Health”, “Ryan White HIV/AIDS Program”, “Health Systems”, and “Rural Health”: *Provided further*, That of the amount made available under this heading, \$1,521,681,000 shall be used for the projects financing the construction and renovation (including equipment) of health care and other facilities, and for the projects financing one-time grants that support health-related activities, including training and information technology, and in the amounts specified in the table titled “Community Project Funding/Congressionally Directed Spending” included for this division in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act): *Provided further*, That none of the funds made available for projects described in the preceding proviso shall be subject to section 241 of the PHS Act or section 205 of this Act.

VACCINE INJURY COMPENSATION PROGRAM TRUST FUND

For payments from the Vaccine Injury Compensation Program Trust Fund (the “Trust Fund”), such sums as may be necessary for claims associated with vaccine-related injury or death with respect to vaccines administered after September 30, 1988, pursuant to subtitle 2 of title XXI of the PHS Act, to remain available until expended: *Provided*, That for necessary administrative expenses, not to exceed \$15,200,000 shall be available from the Trust Fund to the Secretary.

COVERED COUNTERMEASURES PROCESS FUND

For carrying out section 319F-4 of the PHS Act, \$7,000,000, to remain available until expended.

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**42 CFR Part 59**

**RIN 0937-AA11**

**Ensuring Access to Equitable,  
Affordable, Client-Centered, Quality  
Family Planning Services**

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** The Office of Population Affairs (OPA) in the Office of the Assistant Secretary for Health issues this final rule to revise the regulations that govern the Title X family planning program (authorized by Title X of the Public Health Service Act) by readopting the 2000 regulations, with several revisions to ensure access to equitable, affordable, client-centered, quality family planning services for clients, especially low-income clients. The effect of this 2021 final rule is to revoke the requirements of the 2019 regulations, including removing restrictions on nondirective options counseling and referrals for abortion services and eliminating requirements for strict physical and financial separation between abortion-related activities and Title X project activities, thereby reversing the negative public health consequences of the 2019 regulations. OPA also makes several revisions to the 2000 regulations to increase access to equitable, affordable, client-centered, quality family planning services.

**DATES:** This rule is effective November 8, 2021.

**FOR FURTHER INFORMATION CONTACT:**

Jessica Swafford Marcella, Deputy Assistant Secretary for Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; email: [jessica.marcella@hhs.gov](mailto:jessica.marcella@hhs.gov).

**SUPPLEMENTARY INFORMATION:** As described in the 2021 Notice of Proposed Rulemaking (NPRM) (86 FR 19812, April 15, 2021), the Department proposed to revoke the 2019 Title X regulations (84 FR 7714, March 4, 2019) and readopt the 2000 regulations (65 FR 41270, July 3, 2000) with 14 revisions and 10 technical corrections. Revisions were proposed to 59.2, 59.5(a)(1), 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(a)(12), 59.5(a)(13), 59.5(b)(1), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, 59.10,

and 59.11. Technical corrections were proposed to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), 59.8, and 59.12. HHS received comments on all of the revisions proposed in the NPRM, except the revision to 59.11. In addition, the Department received comments on three of the 10 technical corrections, including the technical corrections to 59.5(a)(4), 59.5(a)(5), and 59.12.

Based on the comments received in response to the NPRM, the Department adopts eight of the revisions initially proposed in the NPRM and nine of the technical corrections initially proposed in the NPRM as final without additional changes. This includes the revisions to 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, and 59.11. This also includes the technical corrections to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), and 59.8. Further, based on the comments received in response to the NPRM and a subsequent, new interpretation by the Department since the NPRM was issued, the final rule includes nine additional revisions and six additional technical corrections to what was proposed in the NPRM. The nine revisions include (a) additional modifications to four of the provisions initially revised in the NPRM (59.2, 59.5(a)(1), 59.5(b)(1), and 59.10); (b) additional modifications to one of the provisions with a technical correction in the NPRM (59.5(a)(4)); (c) removal of three of the revised provisions in the NPRM (59.5(a)(12), 59.5(a)(13), and 59.12); and (d) revisions to one provision not originally proposed for revision in the NPRM (59.5(b)(6)). The six additional technical corrections include minor clarifications to 59.2, 59.5(a)(1), 59.5(a)(4), and 59.6 and two technical corrections to 59.5(b)(7) and 59.7 to reflect inclusive language.

Detailed descriptions of all revisions, modifications, and technical corrections are included later in this final rule. In addition to revoking the 2019 rule, this final rule includes the following revisions to the 2000 rule: Adding several new definitions; requiring sites that do not offer a broad range of contraceptive methods on-site to provide a prescription to the client for their method of choice or referrals, as requested; requiring that family planning services be client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and capable of ensuring equitable and quality service delivery; clarifying requirements around billing practices and income verification; enabling a broader range of clinical service providers to direct family

planning services and to provide consultation for medical services related to family planning; clarifying the intent of community education; clarifying the purpose and responsibilities of the Information and Education Advisory Committee; including referral for primary healthcare providers; expanding the grant review criteria to address equity; including language to safeguard client confidentiality; and removing the list of other applicable regulations from the regulatory text.

The Secretary of the Department of Health and Human Services (the Secretary) issues the below regulations establishing requirements for recipients of family planning services grants under section 1001 of the Public Health Service (PHS) Act, 42 U.S.C. 300. The rules below adopt, with the modifications described above, the regulations proposed for public comment on April 15, 2021 at 86 FR 19812. They accordingly revoke the 2019 final rule, *Compliance with Statutory Program Integrity Requirements*, promulgated on March 4, 2019 (84 FR 7714).

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## I. Background

As discussed in the NPRM (86 FR 19812, April 15, 2021), in 2019, the Secretary issued a final rule for the Title X program titled *Compliance with Statutory Program Integrity Requirements*, which substantially revised the longstanding policies and interpretations defining what abortion-related activities were permissible under the program, given Title X's statutory prohibition on abortion services. That statutory prohibition, section 1008 (42 U.S.C. 300a-6), provides that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." The 2000 regulations, which were in effect prior to the 2019 regulations and which reflected compliance standards that had been in effect for nearly the entirety of the Title X program, had been widely accepted by grantees, had enabled the Title X program to operate successfully, and had not resulted in any litigation.

The rules issued on March 4, 2019 (84 FR 7714): (1) Required strict physical and financial separation between abortion-related activities and Title X project activities, (2) required significant reporting by Title X grantees in grant applications and required reports about all subrecipients, referral agencies, or other partners who receive Title X funds, (3) removed the requirement for pregnancy options counseling upon request and permitted nondirective counseling only by an advanced practice provider, (4) prohibited Title X-funded entities from referring for abortion, while requiring referral for prenatal care, regardless of a client's request, and (5) required providers to maintain detailed records on adolescent

clients, including age of their sexual partners and specific actions taken to encourage family participation.

In the 2019 rule, the Department stated that it "believes the provisions of this final rule provide much needed clarity regarding the Title X program's role as a family planning program that is statutorily forbidden from paying for abortion and funding programs/projects where abortion is a method of family planning. The Department believes that the 2000 regulations fostered an environment of ambiguity surrounding appropriate Title X activities." 84 FR at 7721 (March 24, 2019). This belief about the ambiguity, however, lacked any specific evidence. OPA closely monitors Title X grantee compliance through regular grant reports, compliance monitoring visits, and legally required audits, and it has done so since the beginning of the program. Close oversight of Title X grantees for decades uncovered no misallocation of Title X funds by grantees. OPA oversight did identify occasional instances where grantees were in need of updating their written policies to clearly reflect the Title X statutory language, but OPA never found any instance where grantees were co-mingling funds with activities not allowed under the statute or regulations.

In response to concerns that the 2019 rule imposed undue and improper restrictions on grantees, the Department recently conducted a fresh review of the factual assertions that accompanied that rule. In particular, the Department carefully reviewed over 30 Government Accountability Office (GAO), Office of the Inspector General (OIG), and Congressional Research Service (CRS) reports involving the Title X program from 1975 to 2021. Directly contradicting the factual assertions accompanying the 2019 rule, that recent review found only minor compliance issues with grantees—and those only in two GAO reports from the 1980s. Those two reports recommended only more specific guidance, not a substantial reworking of the regulations. *See, e.g.*, Comp. Gen. Rep. No GAO/HARD-HRD-82-106 (1982), at 14-15; 65 FR 41270, 41272 (July 3, 2000). While those forty-year-old reports found some confusion among grantees around section 1008, "GAO found no evidence that Title X funds had been used for abortions or to advise clients to have abortions." Since those reports, there has been no evidence of compliance issues regarding section 1008 by Title X grantees that would justify the greatly increased compliance costs for grantees and oversight costs for the federal government the 2019 rule required.

Experience under the 2019 rule has only underscored these concerns. Based on that experience—which was not and could not have been available to the Department at the time the 2019 rule was promulgated—we have determined that the 2019 rule has led to a diversion of funds from the core purpose of Title X: To provide a broad range of family planning services. Those funds are now being spent on increased infrastructure costs resulting from the separation requirement as well as the micro-level monitoring and reporting now required of grantees. None of these burdensome additional requirements provide discernible compliance benefits, particularly not to public health, and in some instances they are inconsistent with nationally recognized standards of care.

The significant negative public health consequences of the March 4, 2019 rule have become clear over the past two years, and the rule was extremely controversial from the beginning. The rule was immediately challenged in several district courts by 22 states and the District of Columbia, the American Medical Association, Title X grantee organizations, and individual grantees, with support from major medical organizations, including the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Academy of Family Physicians, the Society for Adolescent Health and Medicine, and the Society for Maternal-Fetal Medicine. The 2019 rule was ultimately upheld by an *en banc* Court of Appeals for the Ninth Circuit and enjoined (only as to the state of Maryland) by a district court in Maryland in a decision upheld by the *en banc* Court of Appeals for the Fourth Circuit. Both court of appeals decisions were issued over substantial dissents. In *California v. Azar*, 950 F.3d 1067 (9th Cir. 2020), the Ninth Circuit relied heavily on *Rust v. Sullivan*, 500 U.S. 173 (1991) in upholding the rule. A majority of the *en banc* panel found, consistent with *Rust*, that the Department "could" interpret section 1008 as it did in the 2019 rule, and that nothing in subsequent legislation prevented this reading. *Id.* at 1085. The Ninth Circuit upheld the rule against an arbitrary and capricious challenge, stating "that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better." *Id.* at 1097 (emphasis in original). Conversely, a majority of the Fourth Circuit found the Department's 2019 rule arbitrary and capricious. *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020). The Fourth



Circuit also held that the 2019 rule violated an annual appropriations rider requiring nondirective counseling, the non-directive mandate.<sup>1</sup>

Losing parties in both cases sought review from the Supreme Court in October of 2020. The Court granted certiorari on February 22, 2021, consolidating the cases. No. 20–429. On March 12, 2021, the parties stipulated to dismiss the cases under Supreme Court Rule 46.1.

While courts and judges were split on the ultimate legality of the 2019 rule, evidence of the negative public health consequences of the rule quickly became clear, and significant. After the implementation of the 2019 rule, 19 Title X grantees out of 90 total grantees withdrew from the program. The 19 grantees that withdrew from the Title X program included 11 State Departments of Health and independent Family Planning Associations and eight Planned Parenthood organizations.<sup>2</sup>

These organizations made clear to the Department in formal correspondence that they relinquished their grants out of concern that the 2019 rule interfered with the patient-provider relationship and compromised their ability to provide quality healthcare to all clients. One organization commented that “the Final Rule makes it impossible for us to provide healthcare and information to patients consistent with medical ethics and evidence-based standards of care.” Another organization stated that the 2019 rule “would fundamentally compromise the relationship our patients have with us as trusted providers of this most personal and private healthcare.” Another organization said that “the new regulations interfere with a healthcare provider’s ability to provide healthcare in accordance with accepted standards of care for reproductive health.” Still another said, “these new rules require our providers to deprive their patients of the information and services they

need to make and carry out fully informed decisions about their reproductive health. Our providers’ ethical and professional responsibilities do not allow this.” Although it might have been possible, at the time the 2019 rule was promulgated, to predict that providers would withdraw, any such prediction would have been uncertain. That so many providers did in fact withdraw from the program is a change in circumstances that, in the Department’s view, demands reconsideration of the 2019 rule.

In addition to the grantees that withdrew from Title X completely, many other grantees that continued to receive Title X funding had subrecipients and service sites within their existing networks withdraw from the program. Overall, 19 grantees, including 231 subrecipients and 945 service sites, withdrew from the Title X program shortly after the rule took effect. Additionally, 18 grantees that continued in the program reported losses to their service network (*i.e.*, exiting subrecipients) because of the 2019 final rule. As a result, the Title X program provided services to 844,083 fewer clients in 2019 compared to 2018.<sup>3</sup> Comparing Family Planning Annual Report (FPAR) data for 2018 and 2019, OPA estimates that 94% (or 789,960) of the total decrease (844,083) in clients can be attributed to the 2019 rule. A total of 41 states and two territories saw a decrease in clients served in 2019 compared to 2018. Of those, seven saw a decline of more than 40 percent in clients served (AK, HI, MD, UT, VT, WI, and WV), seven saw a decline of 31–40 percent (CA, CT, ME, MN, NH, NM, and NY), seven saw a decline of 21–30 percent (AZ, IL, MA, MT, NJ, OR, and WA), seven saw a decline of 11–20 percent (IA, IN, MI, OH, PA, VA, and the Marshall Islands), nine saw a decline of 5–10 percent (AL, AR, KY, NE, NC, ND, SC, TN, and WY), and six saw a decline of five percent or less (DE, CO, LA, OK, SD, and the U.S. Virgin Islands). Only nine states, six territories and the District of Columbia saw their number of clients served stay the same (FL, KS, MO, RI, and TX) between 2018 and 2019 ( $\pm 1\%$ ) or increase (GA, ID, MS, NV, six territories, and DC), with the majority experiencing a small annual increase of between 70 to 3,000 clients. Minor fluctuations notwithstanding, 789,960 fewer clients were served, which had a disproportionate impact on minority

clients, adolescent clients, lower-income individuals, and those without insurance—all outcomes directly attributable to the 2019 rule. Most concerning, there are six states that formerly had Title X services that currently have no Title X services available (HI, ME, OR, UT, VT, and WA) and seven states with Title X services available on a very limited basis (AK, CT, IL, MA, MN, NH, and NY). The Department believes that these stark facts, which became clear only after the promulgation of the 2019 rule, justify reconsideration of that rule.

To ensure continuity of services and maintain a safe environment for clients and staff during the pandemic, Title X providers followed guidance issued by the Centers for Disease Control and Prevention (CDC), OPA, and others to manage supply and staffing shortages, and they implemented creative strategies tailored to their circumstances and clientele (virtual telehealth, for example). Despite these efforts, in 2020 vs. 2019, Title X had 193 fewer subrecipients (867 vs. 1,060) and 794 fewer service sites (3,031 vs. 3,825). The decrease in the size of the Title X service network appears to have substantially reduced the availability of and, consequently, access to Title X services. In 2020, Title X served 1.6 million fewer family planning users than in 2019 (1.5 million vs. 3.1 million), and Title X service sites delivered care to 302 fewer users per site (507 vs. 809). Furthermore, in 2020, Title X conducted almost 2.0 million fewer family planning encounters than in 2019 (2.7 million vs. 4.7 million). While the 2020 data undoubtedly reflect the public health emergency related to the COVID–19 pandemic, the pattern of the losses in the program initiated by the 2019 rule was exacerbated in 2020 for an already disrupted and weakened network.

Of additional concern, the 2019 rule has had a disproportionate impact on low-income clients, who are precisely the population that the Title X program was established to serve. The 2019 rule has significantly decreased the number of low-income, uninsured, and racial and ethnic minorities accessing Title X services. Following implementation of the 2019 rule, 573,650 fewer clients under 100 percent of the federal poverty level (FPL); 139,801 fewer clients between 101 percent FPL to 150 percent FPL; 65,735 fewer clients between 151 percent FPL and 200 percent FPL; and 30,194 fewer clients between 201 percent FPL to 250 percent FPL received Title X services. This contradicts the purpose and intent of the Title X program, which is to prioritize and

<sup>1</sup> Both circuit courts also differed on the permissibility of the rule under section 1554 of the Affordable Care Act.

<sup>2</sup> Withdrawn grantees included (1) Family Planning Association of Maine, Inc., (2) Hawaii Department of Health, (3) Health Imperatives, Inc. (MA), (4) Illinois Department of Health, (5) Maryland Department of Health, (6) Massachusetts Department of Public Health, (7) Oregon Health Authority, (8) Planned Parenthood Association of Utah, (9) Planned Parenthood Minnesota, North Dakota, South Dakota, (10 & 11) Planned Parenthood of Great Northwest & the Hawaiian Islands (two separate grants), (12) Planned Parenthood of Greater Ohio, (13) Planned Parenthood of Illinois, (14) Planned Parenthood of Northern New England, (15) Planned Parenthood of Southern New England, (16) Public Health Solutions (NY), (17) New York Department of Health, (18) Vermont Agency of Human Services, and (19) Washington State Department of Health.

<sup>3</sup> (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from <https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf>.

increase family planning services to low-income clients. Additionally, 324,776 fewer uninsured clients were served in 2019 compared to 2018. FPAR data also demonstrate that in 2019 compared to 2018, 128,882 fewer Black or African Americans; 50,039 fewer Asians; 6,724 fewer American Indians/Alaska Natives; 7,218 fewer Native Hawaiians/Pacific Islanders; and 269,569 fewer Hispanics/Latinos received Title X services.<sup>4</sup> Additionally, 151,375 fewer adolescent clients received essential family planning services in 2019. The Department believes these new facts warrant a reconsideration of the 2019 rule.

The mandate of the Title X program is to support access to critical family planning and preventive health services; unfortunately, the result of the 2019 rule ran counter to that effort. The 2019 rule undermined the mission of the Title X program by helping fewer individuals in planning and spacing births, providing fewer preventive health services, and delivering fewer screenings for sexually transmitted infections (STIs). More specifically, in 2019 compared to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008 fewer clients received intrauterine devices (IUDs). Additionally, 90,386 and 188,920 fewer Papanicolaou (Pap) tests and clinical breast exams, respectively, were performed in 2019 compared to 2018. Confidential human immunodeficiency virus (HIV) tests decreased by 276,109. STI testing decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis. Furthermore, 71,145 fewer individuals who were pregnant or sought pregnancy were served.<sup>5</sup>

In the 2019 rule, the Department stated that the rule was “expected to increase the number of entities interested in participating in Title X as grantees or subrecipient service providers and, thereby, to increase patient access to family planning services focused on optimal health outcomes for every Title X client.” 84 FR at 7782 (March 24, 2019). However, this expectation proved unwarranted. Despite several attempts, OPA has been unable to recruit new grantees and new providers into the Title X program to fill the current gaps in services resulting from implementation of the 2019 rule.

First, OPA issued competitive supplemental funding of \$33.7 million to 50 existing Title X grantees in fiscal year 2019 to expand their Title X services. Unfortunately, even with the additional funding, the majority of states were not able to increase the number of service sites in their Title X networks. From 2018 to 2020, 38 states and territories saw a decrease in the number of service sites in their networks, 12 saw no change in their number of service sites, and only nine saw an increase in the number of service sites. Analyzing users between 2018–2020 for those nine states that gained service sites, six still lost users (WV, AZ, DE, NE, CO, and TX) while three gained users (GA, NV, and Palau). Next, OPA issued a competitive funding announcement in fiscal year 2020 to recruit new grantees to provide Title X services in unserved or underserved states and communities. The number of applications received was so low (eight eligible applications received) that the resulting grant awards were for less than the total amount of funding available (grant awards for \$8.5 million with \$20 million available), and OPA was only able to fund grantees to provide services in three states with no or limited Title X services at the time.

The lack of organizations applying for Title X grant funding following implementation of the 2019 rule and the lack of new service sites willing to join existing Title X grantees as providers strongly suggest that the Department was wrong to believe that the 2019 rule would increase the number of grantees and providers. Rather, the 2019 rule appears to have had the opposite effect and resulted in a significant loss of grantees, subrecipients, and service sites, and close to one million fewer clients served from 2018 to 2019. The Department believes that this record warrants a change in course.

The decline in clients served and services provided is devastating. The Title X program is the only federal grant program dedicated to providing comprehensive family planning and related preventive health services. Title X clinics provide services to clients, with priority given to persons from low-income families. Title X services are voluntary, confidential, and provided regardless of one’s ability to pay. For many clients, Title X clinics are their only ongoing source of healthcare and health education. In fact, six in 10 women who go to a publicly funded

family planning clinic consider it their usual source of medical care.<sup>6</sup>

While some family planning providers that withdrew from the Title X program were able to continue providing reproductive health services at some level in the absence of Title X funding, the services provided were not the same as those provided under Title X. Grantees that relinquished their Title X funding at the time made clear that they were not able to provide the same breadth of services as they had been able to under Title X and were not able to provide services using the same schedule of discounts as required in the Title X program. According to several comments received, the loss of Title X funding meant that organizations had to adjust their fee schedules and push more costs for services to the clients. As a result, organizations saw more clients forgoing recommended tests, lab work, STI testing, clinical breast exams, and pap tests. Further, due to costs, organizations saw some family planning clients outside of the Title X network choose less effective methods of birth control.

The 2019 rule abandoned major portions of *Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the U.S. Office of Population Affairs* (QFP),<sup>7</sup> such as nondirective options counseling and referrals, and the client-centered approach recommended by QFP, over the objection of every major medical organization and without any countervailing public health rationale. QFP recommendations support providers in delivering quality family planning services and define family planning services within a broad context of preventive services, to improve health outcomes for individuals and their (future) children. QFP recommendations are based on a rigorous, systematic, and transparent review of the evidence and were developed with input from a broad range of clinical experts, OPA, and the CDC. These recommendations not only improve the quality of care provided to family planning clients, but they foster a supportive and communicative relationship between provider and patient. As evident from grantee relinquishment letters and comments

<sup>4</sup> (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from <https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf>.

<sup>5</sup> (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from <https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf>.

<sup>6</sup> Frost, J., Gold, K., Hasstedt, K., & Sonfield, A. (2014). *Moving Forward: Family Planning in the Era of Health Reform*. New York: Guttmacher Institute.

<sup>7</sup> CDC. (2014). *Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs*. Accessed on March 8, 2021 from <https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning>.

received in response to the 2021 NPRM, abandoning major portions of this approach has damaged the patient-provider relationship. Moreover, the 2019 rule required prenatal referral even if the patient objected, an approach which also does not comport with well-accepted public health and clinical care principles.

On January 28, 2021, President Biden issued a “Memorandum on Protecting Women’s Health at Home and Abroad.”<sup>8</sup> The Memorandum stated that “[w]omen should have access to the healthcare they need. For too many women today, both at home and abroad, that is not possible. Undue restrictions on the use of Federal funds have made it harder for women to obtain necessary healthcare. The Federal Government must take action to ensure that women at home and around the world are able to access complete medical information, including with respect to their reproductive health.” The Memorandum then instructed the Department to “review the Title X Rule and any other regulations governing the Title X program that impose undue restrictions on the use of Federal funds or women’s access to complete medical information and shall consider, as soon as practicable, whether to suspend, revise, or rescind, or publish for notice and comment proposed rules suspending, revising, or rescinding, those regulations, consistent with applicable law, including the Administrative Procedure Act.”

HHS reviewed the 2019 regulations pursuant to the President’s memorandum. Following this review, on April 15, 2021, the Department issued a Notice of Proposed Rulemaking (NPRM) for public comment (86 FR 19812, April 15, 2021), proposing rules to revise the 2019 regulation by essentially readopting the 2000 regulations. 65 FR 41270 (July 3, 2000). The 2000 regulations were consistent with applicable statutory commands, were widely accepted by grantees, enabled the Title X program to operate successfully, and led to no litigation over their permissibility.

Based on the evidence that has emerged since the adoption of the 2019 rule, as well as a fresh consideration of the evidence that existed at the time, the negative public health consequences of the 2019 rule are clear. The rule dramatically reduced access to family planning and preventive health services that are essential for hundreds of

thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to family planning services within states across the country and in rural and urban communities alike. The 2019 rule shifted the Title X program away from its history of providing client-centered quality family planning services and instead set limits on the patient-provider relationship and the information that could be provided to the patient by the provider. The 2019 rule resulted in increased costs for grantee reporting that are unnecessary for ensuring grantee compliance. Continued enforcement of the 2019 rule raises the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations and other disproportionately impacted communities, such as those in rural regions, minority clients, and adolescent clients, are relegated to inferior access. The populations served by Title X may already face health inequities driven by financial and access barriers to quality care that would be exacerbated by continuing to allow limited or delayed healthcare choices and biased or insufficient healthcare information. Given that so many individuals depend on the Title X program as their primary source of healthcare, the Department recognizes that this is a situation that must be rectified with urgency in the interest of public health and equity.

Most importantly, in readopting the 2000 rule, this final rule removes the strict physical separation requirements that were imposed on top of existing obligations for separation between abortion services and Title X project related activities. It also allows Title X providers to provide truly nondirective counseling and refer their patients for all services desired by the client, including abortion services. The 2000 regulations successfully governed the Title X program for decades and were widely accepted by grantees.

The 2019 rule imposed an interrelated set of requirements that are difficult to disentangle provision by provision. For example, 59.5(a)(5) prohibited funded projects from providing, promoting, referring, or supporting abortion as a method of family planning. Section 59.13 concurrently required assurance that a project did not “include abortion as a method of family planning” backed by documentary evidence of Subsections 59.14–59.16. The interrelatedness of these requirements

was underscored by 59.7(b) requiring applicants to “clearly address how the proposal will satisfy the requirements of the regulation,” before even proceeding to competitive consideration. Most of the 2019 provisions did not function independently of each other.

The Department did initially propose keeping portions of two provisions from the 2019 rule regarding compliance reporting (59.5(a)(12)) on state sexual abuse notification laws and subrecipient monitoring (59.5(a)(13)). As further explained below, these provisions created administrative costs for grantees and the government with no measurable benefits. These provisions, like the entire 2019 rule, depended on assumptions about how the program should work and grantee compliance even with no evidence of grantee non-compliance.

Given these considerations, the Department has determined that the most appropriate course is to revoke the 2019 rule in its totality. Every court to rule on the 2019 rule also believed that all of its provisions were of a piece and either struck down or upheld the rule in its entirety. See, e.g., *Mayor of Baltimore v. Azar*, 973 F3d 258, 292 (4th Cir. 2020) (“Despite the severability clause, the Final Rule is not severable because it is clear HHS ‘intended the [Final Rule] to stand or fall as a whole,’ and the agency desired ‘a single, coherent policy, the predominant purpose of which’ is to reinstitute the 1988 Rule.”).

As compared to the 2019 rule, new provisions added to the re-adoption of the 2000 rule operate independently of each other—and the 2000 rule—to enhance the program. Particularly as the program operated for decades under the 2000 rule, the 2021 additions are severable from the 2000 rule. For example, while adding to the statutory goals of reaching low-income and underserved individuals, if the added grant evaluation criteria of equity, 59.7(a)(3), was excised, the program could still accomplish its mission successfully using the 2000 criteria alone. And, were a court to strike down the new income verification measures in 59.5(a)(9), the program would be able to accomplish its mission using the 2000 criteria alone.

In addition to readopting the requirements as they existed prior to the 2019 rule, the 2021 rule also includes several revisions that will strengthen the Title X program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients, while retaining the longstanding prohibition on directly promoting or performing abortion that follows from

<sup>8</sup> Available at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/28/memorandum-on-protecting-womens-health-at-home-and-abroad/>.



Section 1008's text and subsequent appropriations enactments.

Advancing equity for all, including people from low-income families, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for the Department, for OPA, and for the Title X program. By focusing on advancing equity in the Title X program, we can create opportunities to support communities that have been historically underserved, which benefits everyone. The 2021 rule was written to ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access. Key strategies for advancing equity include removing barriers to accessing services, improving the quality of services, and providing services that are client-centered. Several revisions in the rule focus on improving access to services. These revisions include clearly defining what constitutes a broad range of acceptable and effective family planning methods and services, requiring service sites not offering a broad range of methods on-site to provide a prescription to the client for their method of choice or referrals, as requested, clarifying required billing practices and income verification for low-income clients, enabling a broader range of clinical services providers to direct Title X services and to provide consultation for medical services, and strengthening client confidentiality.

Several revisions in the 2021 rule focus on improving quality of Title X services. These revisions include clearly defining quality healthcare as safe, effective, client-centered, timely, efficient, and equitable; incorporating QFP's definition of family planning into the regulation; and requiring all family planning services to be delivered consistent with nationally recognized standards of care. Finally, several revisions in the 2021 rule focus on ensuring client-centered care. These revisions include clearly defining client-centered care as being respectful of, and responsive to, individual client preferences, needs, and values and where client values guide all clinical decisions, and requiring all family planning services to be client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed.

## II. Public Comment and Departmental Response

The Department provided a 30-day public comment period for the proposed rule. That period closed on May 17, 2021. A total of 180,266 public comments were submitted to [www.Regulations.gov](http://www.Regulations.gov) or directly to the Department.

With this 2021 final rule, the Department revokes the requirements of the 2019 regulations (84 FR 7714, March 24, 2019) and readopts the 2000 regulations (65 FR 41270, July 3, 2000) with several revisions. In the section below, the Department discusses the public comments, its responses, and the text of the final rules. The Department first presents a summary of public comments received related to revoking the 2019 regulation and readopting the 2000 regulation. The Department then provides a summary of comments received regarding the revisions and technical corrections proposed in the NPRM to specific provisions of the 2000 regulations. The NPRM proposed 14 revisions, including to 59.2, 59.5(a)(1), 59.5(a)(3), 59.5(a)(8), 59.5(a)(9), 59.5(a)(12), 59.5(a)(13), 59.5(b)(1), 59.5(b)(3), 59.5(b)(8), 59.6, 59.7, 59.10, and 59.11. The NPRM also proposed 10 technical corrections, including to 59.2, 59.5(a)(4), 59.5(a)(5), 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(3), 59.6(b)(2), 59.8, and 59.12. The Department received comments on all the revisions proposed in the NPRM and three of the 10 technical corrections. The Department did not receive comments on the revision to 59.11, nor to the technical corrections to 59.2, 59.5(a)(6), 59.5(a)(7), 59.5(a)(11), 59.5(b)(2), 59.5(b)(3), or 59.8. A summary of comments and the Department's response are only provided for those revisions and technical corrections that received comments. In addition, the Department received public comments requesting a revision to 59.5(b)(6) that was not proposed in the NPRM, but that is related to the revision that was proposed in the NPRM to 59.5(b)(1). A summary of these comments and the Department's response are also included below.

After considering the comments, the Department adopts the regulations proposed for public comment on April 15, 2021 at 86 FR 19812 with nine additional revisions and six additional technical corrections to what was proposed in the NPRM.

General Comments Related To Revoking 2019 Regulations and Readopting the 2000 Regulations

*A. Compliance With Section 1008 (42 U.S.C. 300a-6)*

*Comments:* Thousands of comments expressed concern that the program's returning to the 2000 regulations violated both the Title X statute and the Court's holding in *Rust v. Sullivan*, 500 U.S. 173 (1991). Many comments stated referral for abortion "squarely" violated the "plain" "clear" text of section 1008. Many of these same comments also asserted the statute requires separation from abortion activities because they are programs "where" abortion is a method of family planning. Both comments believing the 2000 rule to be unlawful, and those affirming it to be lawful, cited *Rust* as well as legislative history in making their arguments.

Those opposing the proposed rule also stressed that private organizations have no right to federal funding, much less to federal funding to perform abortions. These comments stated that "[m]oney is fungible," and reverting to the 2000 rule will create so-called "slush funds" and infrastructure for organizations to perform abortions in violation of section 1008. They also suggested that the 2000 rule lacked any mechanism to ensure compliance with the statute, and that the NPRM, in fact, violates the statute because the proposed definition of "family planning" includes related "pregnancy counseling" which requires referral for abortion when requested (59.5(a)(5)). Many comments asserted that revoking the 2019 rule would allow grantees to engage in lobbying and other activities encouraging abortion that violate section 1008.

*Response:* As stated in the NPRM, the Supreme Court held in *Rust*: "[W]e agree with every court to have addressed the issue that the language is ambiguous. The language of § 1008—that 'none of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity." *Rust* at 184. No court adjudicating the 2019 rule found that the separation, referral, or other requirements were required by *Rust*. Such a finding would be contrary to the primary holding in *Rust*. Counseling for abortion, including referral when requested, has never been held to constitute a violation of section 1008.

Interpreting section 1008 to prohibit referrals and require strict separation would also be inconsistent with nearly

40 years of agency practice under the program across numerous administrations. Such an interpretation would also appear contrary to decades of close Congressional oversight, including annual Title X appropriations riders, and a specific annual line item appropriation through which Congress can be—and has been—quite clear as to how the agency should operate.

In readopting the 2000 rule, the program is also reinstating interpretations and policies under section 1008 of the statute that were in place for much of the program's history and published in the **Federal Register** in 2000. 65 FR 41281 (July 3, 2000). Those program policies discuss, for example, the requirements for separation: "Separation of Title X from abortion activities does not require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008." 65 FR at 41282 (July 3, 2000). Also, "[w]hile a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient." 65 FR at 41281 (July 3, 2000). Finally, while a Title X project may not advocate for abortion as a method of family planning, it "may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project)." *Id.* Interested entities are encouraged to consult this notice.

The Department agrees that it is not under a duty to subsidize abortion. It does not do so, and it is prohibited from doing so. As discussed in the NPRM, legislative history and longstanding appropriations riders prohibit Title X funds from being expended on abortion. See, e.g., Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 207, 134 Stat. 1182, 1590. More generally, Section 507 of the Consolidated Appropriations Act, 2021 prohibits federal funds from being used for abortion except for cases of rape, incest, or maternal health. *Id.* at sec. 507. As discussed in the NPRM and

above, the Department employs a variety of mechanisms to enforce such restrictions, such as regular grant reports, compliance monitoring visits, third-party audits, compliance guidance, and grantee education. None of these oversight tools have uncovered any more than minimal problems with grantee compliance under section 1008.

The Department also agrees that no particular private organizations have a right to Title X funding. The program is returning to the program requirements in operation for the majority of its history because those requirements best serve individual clients and the public health. In the wake of the 2019 rule, both private organizations and states withdrew from the program, leaving multiple states without any Title X providers and the agency struggling to meet its mandate to provide family planning services for low-income populations in areas of high need. Though in some places organizations and jurisdictions were able to temporarily provide resources to replace the loss of Title X funds, providers were not always able to provide the same scope of services or seamless care coordination that Title X projects can provide. Public comments from those organizations made clear that they were not able to provide the same breadth of services, nor were they able to provide services with the same schedule of discounts for low-income clients.

The Department disagrees that Title X grant funds allow for the "creation of slush funds" or that those funds are "fungible." As stated above, the Department has multiple methods by which it confirms that grant funds are spent for grant purposes, and it has concluded that grantees comply, not just with section 1008, but with Congressional directives and other requirements of the program. Again, the 2019 rule could point to no significant compliance issues related to the diversion of Title X grant funds, and a fresh review of decades of evidence has uncovered no such issues. A ban on organizations receiving Title X funds for lawful activities outside of the Title X project would go beyond the 2019 rule and raise serious constitutional issues. And even if such a restriction might conceivably be lawful, the Department clearly has the discretion to open eligibility to the most qualified Title X providers.<sup>9</sup>

<sup>9</sup> Zolna, M.R., & Frost, J.J. (2017, August 2). *Publicly funded family planning clinics in 2015: Patterns and trends in service delivery practices and protocols*. Guttmacher Institute. Retrieved from <https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015>.

## *B. Data on Negative Public Health Consequences of 2019 Rule*

*Comments:* A few comments took issue with data presented in the NPRM. They stated that the Department used flawed data and failed to account for the effects of COVID-19, instead attributing the loss of grantees and subrecipients and the decline in services to the 2019 rule. One comment stated that the Department does not have data to assess the effect of the 2019 rule. Another comment argued that the decline in clients served is the result of a long time decline since the 2000 rule. One of those same comments reflected the belief that the decline in services is instead related to changes in insurance, changes in poverty, and use of the most effective contraceptive methods, and that declines have been continuous since 2000.

Some of the comments also took issue with the Department's position that the withdrawal of grantees from the program in response to the 2019 rule resulted in a decline in services, as they stated those services were continued with state and private funds and not discontinued, and the Department's claims of fewer services provided is "a red herring." The same comment pointed out the proposed rule noted that seven states saw an increase in clients after the 2019 rule. Another comment cited Planned Parenthood data showing that Planned Parenthood provided more services in 2020 compared to 2019 and that other providers stepped in to fill the gaps in services left when Planned Parenthood exited the Title X program. It cited Ohio as an example and said that additional clients would be served post-COVID-19. A final opposing comment claimed that the number of new providers applying for Title X funds increased after the publication of the 2019 rule.

In contrast, numerous comments supported the 2021 NPRM and shared data on the negative impact that the 2019 rule has had in their states and communities, reinforcing the Department's statements in the NPRM. Many of the comments spoke to the drastic reduction in clients they were able to serve after the 2019 regulation. One comment stated, "throughout the history of Title X, since its inception in 1970, there has never been as sharp a decline in the number of patients served by the program as occurred between 2018 and 2019." More than losing numbers of clients, numerous comments spoke to the types of clients they have not been able to serve and the nature of services that are being lost because clients cannot afford those services.

Several comments noted that the 2019 regulation is disproportionately impacting rural regions, minority clients, adolescent clients, lower-income individuals, and those without insurance, particularly in states that have not expanded Medicaid.

Contrary to the comments that expressed Planned Parenthood affiliates were able to provide more services after leaving the Title X program, Planned Parenthood affiliates themselves, in addition to other commenters, indicated that without Title X funding, they have had to adjust their sliding fee scales, pushing more costs onto the clients. Comments stated that this has resulted in clients forgoing recommended tests, lab work, STI testing, clinical breast exams, and Pap tests in large numbers. Further, these comments provided evidence that some clients are choosing less effective methods of birth control due to costs. Other comments stated that the changes in fees have pushed their clients into seeking care elsewhere, interrupting their continuity of care. One comment reported that the loss of Title X funding resulted in loss of eligibility for the 340B Drug Pricing Program, requiring the agency to dispose of contraceptive methods purchased under the 340B Program and repurchasing them at higher market prices.

The Attorneys General of 22 states and the District of Columbia commented that the emergency, one-time,<sup>10</sup> and private funding made available to replace the loss of Title X funding has strained state budgets and could not be sustained, creating uncertainty for the future of their family planning providers. Additionally, several comments noted that the fundraising activities necessitated after leaving the Title X program have come at a cost and have resulted in providers having to scale back or eliminate educational and outreach programs in many states. Other comments noted that it was extremely burdensome to try to identify and recruit additional providers to fill the gaps left after the 2019 rule. Many commenters expressed strong interest in rejoining the Title X network once the current rule is replaced. Finally, several states reported that while their efforts were refocused on recruiting and onboarding new providers into their Title X network under the 2019 rule, they faced much resistance and/or a lack of interest, and their provider networks did not increase under this

rule, continuing to adversely impact the communities they serve.

*Response:* The Department believes that the negative public health consequences of the 2019 rule are clear. The rule dramatically reduced access to essential family planning and related preventive health services for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to essential family planning services within states and communities across the country.

The Department disagrees that the data cannot distinguish between enactment of the 2019 rule and the pandemic. The 2019 rule officially took effect mid-year in 2019, but COVID-19 was not announced as a national emergency until early 2020. The Department has data to assess the impact of the 2019 rule through FPAR and grantee progress reports, including data on the decrease in the number of clients served in 2019 when the rule was in place and prior to COVID-19. As stated in the Background section, 19 grantees, 231 subrecipients, and 945 service sites immediately withdrew from the Title X program. As a result, the Title X program provided services to 844,083 fewer clients in 2019 compared to 2018, prior to the implementation of the 2019 rule, approximately a 22 percent decrease. A total of 41 states and two territories saw a decrease in clients served in 2019 compared to 2018; five states saw their number of clients served stay the same; and four states, five territories, and the District of Columbia saw an increase in clients served from 2018 to 2019, with the majority experiencing a small annual increase of between 70 to 3,000 clients. Minor fluctuations notwithstanding, 844,083 fewer clients were served, disproportionately impacting lower-income individuals, minority clients, adolescent clients, and those without insurance. There are currently six states with no Title X services available and seven states with Title X services available on a very limited basis. Ultimately, the hundreds of thousands of clients who lost access to Title X services as a result of the 2019 rule lost access to critical family planning and preventive health services. As noted in the background, this included declines in contraceptive services, Pap tests, clinical breast exams, and HIV and STI testing.

The Department agrees that a few states were able to increase their service sites following the 2019 rule, but these

are the exception. From 2018 to 2020, 34 states and territories saw a decrease in the number of service sites in their network, 18 saw no real change in their number of services sites, and only seven saw an increase in the number of service sites. OPA attempted to recruit new grantees to provide Title X services through a competitive funding opportunity, but OPA only received eight applications and was only able to provide services in three of the states with no or limited Title X services at the time. Some comments opposing the 2021 NPRM specifically cited Ohio as an example of a state that would be able to increase clients served post-COVID-19. Despite the state health department receiving additional funds to provide Title X services following the departure of another grantee, FPAR data from Ohio, however, do not provide any clear support for this claim and reinforce that capacity among entities is not necessarily equivalent. According to the FPAR data from Ohio, the state experienced a 10 percent decline in service sites between 2018 and 2020, an 18 percent decline in clients from 2018 to 2019, and a 57 percent decline in clients from 2019 to 2020. While many states and territories experienced a decline in clients from 2019 to 2020 due to COVID-19, Ohio's percentage decline in clients from 2019 to 2020 ranked 18th in order of states from largest decline to smallest decline. Seventeen states experienced a larger decline in clients from 2019 to 2020, and 41 states and territories experienced a smaller decline in clients. The data show that even if the same amount of funding is provided to a different set of grantees in a given area, it does not necessarily follow that the same number of clients will be served or same number of services will be provided, depending on the differences in grantee service capacity. Existing Title X grantees also experienced great difficulty recruiting new sites and new providers into their existing Title X networks under the 2019 regulations, as evidenced by the lack of states experiencing an increase in their number of service sites. Overall, it is clear that the 2019 rule directly resulted in a significant loss of grantees, subrecipients, and service sites, and close to one million fewer clients served from 2018 to 2019.

While some states and organizations were able to provide family planning and related preventive health services in the absence of Title X funding, the comments made clear that they were not providing the full scope of services provided under the Title X program, they were not provided following the

<sup>10</sup> States that provided emergency funding include CA, MA, MD, NY, OR, WA, and VT.



same standards as in Title X, and the same schedule of discounts and subsidies were not applied as required in the Title X program. Finally, many of the states that provided emergency or one-time funds, or those organizations that were able to raise funds privately, indicated through their comments that they could only do so on a very short-term basis, that it was not sustainable for the long term, and that it came at a price—requiring elimination of other critical services.

Given the data presented in the preamble and the data presented above, the Department disagrees with the claim that Title X services would improve after COVID-19 (absent a change in the 2019 rule). The loss in clients served, the states with no service providers, and the states with limited service providers occurred in 2019 after enactment of the 2019 rule and prior to COVID-19, making it unlikely that the number of clients served or services provided would increase to pre-2019 levels or above without a change to the 2019 rule. Comparing FPAR data for 2018 (“typical year”) and 2019 (post 2019 rule but pre-COVID), OPA estimates that 94% (789,960) of the total decrease (844,083) in family planning clients between 2019 and 2020 can be attributed to the 2019 rule. Further comparing FPAR data for 2018 (“typical year”) and 2020 (post-COVID), OPA estimates that 63% (or 1.5 million) of the total decrease (2.4 million) in family planning users between 2018 and 2020 can be attributed to the final rule. The grantees and subrecipients that left the program have indicated that they will not return to the program under the 2019 rule. Coupled with the lack of additional applicants to the Department’s funding opportunity, the Department maintains the decline in access, clients, and services from 2018 levels will continue until a new rule is in place.

### *C. Grantee and Subrecipient Compliance*

*Comments:* Several comments expressed concern that the 2021 NPRM did not include language from 59.1 in the 2019 rule, stating, “the requirements imposed by these regulations apply equally to grantees and subrecipients.” Several comments also expressed concern that the 2021 NPRM did not include language from 59.13 specifically requiring grantees to provide assurance that their project does not provide abortion and does not include abortion as a method of family planning. One comment stated that “[t]he removal of an explicit compliance requirement, without at minimum an explanation that subrecipients are assumed to have

to comply with all Title X regulations, suggests that such compliance is no longer required.”

Another comment claimed that the departure of providers from the Title X network after the introduction of the 2019 rule confirmed that Title X funding had been used by those providers for impermissible purposes. Additionally, the comment claimed that the withdrawal demonstrates an unwillingness to comply with program requirements, and that “healthcare providers were accepting Title X funding for years without complying with the statutory requirements of the program.”

*Response:* The Department disagrees with the comments and does not believe that it is necessary to include language within the Title X regulations stating that the regulations apply equally to grantees and subrecipients because this is already a requirement in the HHS grants regulations that apply to Title X grantees. All Title X grantees are subject to 45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. In fact, Title X Notices of Funding Opportunity (NOFOs) state that successful applicants that accept an award agree that the award and all activities under the award are subject to all provisions of 45 CFR part 75. Specifically, 45 CFR 75.352 sets out the requirements for pass-through entities and clearly specifies that “all pass-through entities must (a) ensure that every subaward is clearly identified to the subrecipient as a subaward and includes the following information at the time of the subaward and if any of these data elements change, include the changes in subsequent subaward modification ..... Required information includes ..... (2) All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award.” Given that Title X grantees are required to follow 45 CFR part 75, and since 45 CFR part 75 makes clear that all requirements of the grant, including federal statutes, regulations, and terms and conditions of the federal award, apply to all subrecipients, the Department believes it is clear that the Title X regulations will continue to apply equally to all grantees and subrecipients without needing to include separate language in the Title X regulations.

Similarly, the Department does not deem it necessary to include language within the regulation itself requiring

grantees to provide assurance that their project does not provide abortion and does not include abortion as a method of family planning. The Department has explicitly stated in all NOFOs that all grantees must comply with the Title X statute, regulations, and legislative mandates, and applicants certify in the application materials that they “[w]ill comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.” Additionally, compliance with program statutes and appropriations act requirements is included as a standard term of the grant award. Therefore, during the application process, and by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates.

The Department also disagrees with the contention that withdrawal of organizations following the 2019 rule proves that these organizations were non-compliant with the statutory requirements. The primary reasons cited by most grantees for withdrawing from the Title X program after promulgation of the 2019 rule was out of concern that the 2019 rule interfered with the patient-provider relationship and compromised their ability to provide quality healthcare to all clients. For certain grantees, the regulation was also in direct conflict with laws established by their state.

Furthermore, there is no evidence to suggest that the grantees that withdrew from the Title X program had had any difficulties complying with the Title X statute, regulations, or legislative mandates. OPA practices, and practiced long before the 2019 rule, robust monitoring processes to ensure grantee compliance with the statute and regulations, including through regular grant reports, compliance monitoring visits, and legally required audits. As stated in the Background section, close oversight of Title X grantees for almost two decades under the 2000 rule uncovered no misallocation of Title X funds by grantees. OPA oversight did identify occasional instances over the years where grantees needed to update their written policies to clearly reflect the Title X statutory language, but OPA never found any instance where grantees were co-mingling funds with activities not allowed under the statute. The Department believes that grantee compliance with the Title X statute and regulations has not been an issue throughout the history of the Title X program, and the compliance monitoring methods that have historically been applied by OPA prior to the 2019 rule have ensured that



grantees have an understanding of the statute and how to comply with it. The Department rejects as without merit the comments that these grantees were accepting Title X funding for years without complying with statutory requirements. Neither the 2019 rule itself nor any comments to the 2021 NPRM cited evidence of widespread noncompliance.

#### *D. Application of Conscience and Religious Freedom Statutes to Title X*

*Comments:* The Department received thousands of comments on the preamble language concerning the application of the conscience statutes to Title X. As further discussed in the NPRM, Congress has passed several laws protecting the conscience rights of providers, particularly in the area of abortion. For instance, under 42 U.S.C. 300a-7, the Church amendments, grantees may not require individual employees who have objections to abortion to provide such abortion counseling, or those who have objections to sterilization procedures to perform, assist in the performance of, or provide counseling regarding sterilizations. Since 2005, Congress has also annually enacted an appropriations rider, the Weldon amendment, which extends non-discrimination protections to other “health care entities” who refuse to counsel or refer for abortion. See, e.g., Consolidated Appropriations Act, 2021, Public Law 116-260, Div. H, section 507(d) (2020). Under these statutes, objecting providers or Title X grantees are not required to counsel or refer for abortions.

Many commenters expressed a belief that the statutory conscience protections prohibited the agency from promulgating any counseling or referral requirements. Conversely, some asserted that the conscience statutes have no bearing on what requirements Title X could impose on grantees by regulation. Many comments asserted that these statutes had to be incorporated into the Title X regulatory text for them to be operative or the rule to be lawful. Some stated that the statutes themselves violated the separation between church and state. Several other comments cited a concern that applications from providers objecting to abortion counseling or referral would not be favorably evaluated. Many also suggested that the Department should simply allow for abortion counseling and referral rather than requiring it, since the conscience statutes protect objecting providers from those requirements in any case.

Beyond the Church and Weldon Amendments, a few comments also

stated that requiring abortion counseling or referral automatically violated the Religious Freedom Restoration Act (RFRA), 42 U.S.C. 2000bb through 42 U.S.C. 2000bb-4. At least one comment suggested that the counseling and referral requirements coerced speech in violation of the First Amendment for those providers who object.

*Response:* The conscience statutes have been the subject of multiple rulemakings and numerous lawsuits in the last 13 years. Most recently, the Department finalized a rule in 2019 providing definitions and an enforcement mechanism for several statutes protecting medical providers who have conscience-based objections to certain activities. *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 FR 23170 (May 21, 2019). That rule was vacated by three different courts. *New York v. HHS*, 414 F. Supp. 3d 475, 536 (S.D.N.Y. 2019) (appeal in abeyance); *Washington v. Azar*, 426 F. Supp. 3d 704, 722 (W.D. Wash. 2019) (same); *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019) (same). While the statutes may at times interact with the requirements of Title X, interpreting these laws is beyond the scope of this rule and the HHS Office for Civil Rights (OCR) has been delegated authority to receive complaints under these provisions.

Moreover, as the DC Circuit pointed out when the Weldon Amendment was enacted and the 2000 Title X rule was in effect, “a valid statute always prevails over a conflicting regulation,” *Nat’l Family Planning & Reprod. Health Ass’n v. Gonzales*, 468 F.3d 826 (D.C. Cir. 2006). This is true whether an overriding statute is incorporated into regulatory text or not. The applicability of other rules and laws are best evaluated by consulting those rules and laws and then seeking guidance from the agencies responsible for implementing them. Particularly in areas where the administrative rules may be modified or statutory directions may change from appropriation to appropriation, it is unwise for OPA to formalize interpretations beyond its own statutory authority.

Irrespective of the points made above, as recounted in the NPRM, objecting individuals and grantees will not be required to counsel or refer for abortions in the Title X program in accordance with applicable federal law. OPA has long worked with grantees and providers to ensure appropriate compliance with conscience laws as well as continuity of care. As stated above, OCR has been delegated authority to receive any complaints

related to the conscience protections and will continue to enforce them. As discussed in the NPRM, recognition of provider conscience rights has been the position of the Department since before the 2000 rule. See 65 FR at 41274 (2000 rule, stating that under “42 U.S.C. 300a- (d), “grantees may not require individual employees who have such objections to provide such counseling.”). However, as also discussed in the 2000 final rule, the Secretary was unaware then—and is still unaware—“of any current grantees that object to the requirement for nondirective options counseling.” *Id.*

Just as non-objecting providers should not dictate the provision of information and referrals by those who do object, the existence of statutory conscience protections for providers does not preclude other willing providers from providing referrals or counseling for abortion within the program. With this final rule, the Department is emphasizing the importance of ensuring access to equitable, affordable, client-centered, quality family planning services. Client-centered care is defined as being respectful of, and responsive to, individual client preferences, needs, and values, and ensures that the client’s values guide all clinical decisions. With an emphasis on providing services that are client-centered, the default should be the fullest provision of information to clients. Providers may avail themselves of existing conscience protections and file complaints with OCR, which will be evaluated on a case-by-case basis as is done with other complaints.

As noted in previous iterations of both sets of rules, the conscience provisions and Title X rules have existed side by side for decades with very little conflict, or even interaction. From 1993 to 2017, Title X received no reports of grantees or individuals objecting to the regulatory requirement to counsel or refer for abortions when requested. See *Nat’l Family Planning & Reprod. Health Ass’n*, 468 F.3d at 830 (“[T]here are structural reasons to doubt that the issue will ever come up. In 2000 HHS Secretary Shalala declined to create a specific exception from the pending [Title X] regulation’s mandatory referral requirement for organizations resisting provision of abortion counseling or referrals; she explained that she was “unaware of any current grantees that object to the requirement for nondirective options counseling, so this suggestion appears to be based on more of a hypothetical than an actual concern.”). As with any issue facing Title X grantees and applicants, the program will work to provide guidance to grantees and coordinate any

conflicts with the OCR. A case-by-case approach to investigations will best enable the Department to deal with any perceived conflicts within fact-specific situations.

The Department declines to definitively interpret RFRA or the First Amendment in this context for largely the same reasons. Not only do the conscience protections more specifically allow providers to object to referral and counseling for abortion requirements, but the Title X rules in force for decades prior to the 2019 rule also existed side by side with RFRA and the First Amendment with no conflict. However, in light of the comments received, and to eliminate any confusion, the Department has noted in this final regulation that “[p]roviders may separately be covered by federal statutes protecting conscience and/or civil rights.”

#### *E. Options Counseling*

*Comments:* The Department received thousands of comments expressing support for “the reinstatement of the requirement to offer nondirective options counseling to pregnant patients.” Many comments expressed support for reversing the 2019 rule’s restrictions on what referrals can be provided to clients and allowing providers to offer patients complete information about their healthcare options and refer patients to providers who offer services to meet those needs. One comment stated that “reinstating the 2000 regulations would remove this undue governmental interference into medical care and will help ensure patients receive medically accurate, comprehensive information from their physicians.”

The Department also received comments in opposition to removing restrictions on referring for abortion services and requiring nondirective counseling. Several comments opposed removing restrictions on what referrals can be provided to clients in general, and a few opposed removing restrictions which state that only advanced practice providers can provide nondirective counseling. Many comments opposing the rule expressed a belief that the information and counseling requirements in this provision violate section 1008 of the Title X statute. Others believed that requiring “that grantees refer (sic) individuals to abortion providers conflicts with the free speech and religious freedom of grantees.” Still others expressed concern that the requirement could limit the type of providers in the program due to conscience concerns.

*Response:* The Department appreciates the comments in support of this provision. The Department believes that offering pregnant clients the opportunity to receive neutral, factual information and nondirective counseling on all pregnancy options—and providing referral upon request for option(s) the client wishes to receive—are critical for the delivery of quality, client-centered care. The Department agrees that restoring this provision will remove unnecessary limitations governing the patient-provider relationship and will enable healthcare providers to offer complete and medically accurate information and counseling to their clients.

The Department’s response to comments opposing this provision is included earlier in Section II. A. *Compliance with Section 1008 (42 U.S.C. 300a-6) and D. Application of Conscience Statutes to Title X.* The NPRM language for this provision would restore the regulatory text from the 2000 regulation, which successfully governed the Title X program for decades without opposition from major medical organizations and was widely accepted by grantees.

#### *F. Subrecipient Nondiscrimination*

*Comments:* The Department received many comments on state policies restricting subrecipient participation for reasons unrelated to the provider’s ability to provide care. The majority of these comments favored a regulatory prohibition on such restrictions because they often exclude the best family planning providers for no discernible purpose. Many comments stated that “State policies putting restrictions on how state funds are allocated, called ‘tiering,’ make it difficult or impossible for privately operated reproductive health-focused providers to receive funding. Tiering and other prohibitions against abortion providers often exclude the specialist providers that are the most qualified and best equipped to help Title X patients achieve their family planning goals.” Such restrictions, which are in place in approximately 15 states, can make access for certain subpopulations and geographic areas more difficult. Many comments stressed that “expelling well-qualified, trusted family planning providers from publicly funded health programs like Title X has adverse effects on patients’ access to critical family planning and sexual healthcare.”

The Department also received many comments, including from multiple state Attorneys General, condemning any regulation in this area. Many of these objections stated that such a

regulation would undermine federalism and “intrude on the States’ self-governance for no good reason,” and, most prominently, violate the Congressional Review Act, 5 U.S.C. 801–808. Under that law, an agency may not promulgate a rule that is “substantially the same” as one that has been disapproved by Congress. In 2016, the Department enacted a rule barring projects from rejecting sub-grantees for non-programmatic reasons. 81 FR 91852 (Dec. 19, 2016). Congress subsequently revoked the rule. P.L. 115–23 (4/13/2017). Multiple comments asserted that any regulation in this area would be unlawful unless Congress specifically authorized it.

*Response:* All proposed additions to the 2000 rule received an overwhelmingly positive response, except the proposal to include a subrecipient non-discrimination provision. After carefully considering several factors, the agency is declining to include a subrecipient non-discrimination provision in this rulemaking. Foremost among the Department’s considerations is the sense of urgency in the interest of public health to complete this rulemaking. This schedule allows for a final rule to be effective before the award of the next round of competitive funding for the Title X program. This, in turn, will enable applicants that previously withdrew from participation in the program as a result of the previous regulation to apply for funding.

The Department still believes state restrictions on subrecipients unrelated to care hamper the ability of the program to achieve its goals. However, the overriding task of this rulemaking is to undo the negative public health effects of the previous rule. That result is most effectively reached by not including a subrecipient non-discrimination provision in this rulemaking. Organizations in states with restrictive laws may still apply directly to receive Title X grants (*see* PHS Act sec. 1001(b); 59.3).

#### *G. Other Comments*

*Comments:* While many comments were specific to certain sections of the proposed rule, a sizeable number were more general in nature, or commented on portions of the preamble. Many of these general comments were summarized in detail in the sections above, and the remainder of the general comments are summarized here.

Of those that support the proposed rule, a large number of comments expressed general support for removing the harmful effects of the 2019 rule on Title X services. A similarly large

number felt that the 2019 rule negatively impacted the number of clients served and that the proposed rule will increase the number of clients served. Many comments supported being able to expand access to Title X services across the nation and within states and territories. They felt that the proposed rule will result in more Title X grantees and service sites and will increase the diversity of grantees. Many other comments expressed support that the proposed rule will increase health equity and decrease health disparities by increasing the number of marginalized and vulnerable groups served by Title X.

Many comments expressed a belief that the proposed rule will result in improved health outcomes and that the 2019 rule had a negative impact on public health. Others supported the emphasis in the proposed rule on quality family planning and felt that the proposed rule will result in improved quality of care. Many comments expressed a belief that the proposed rule better aligns with the mission of Title X and that it will result in cost savings.

Of those that oppose the proposed rule, many expressed general opposition to the elimination of the 2019 rule, and a large number expressed a belief that the proposed rule does not align with the mission of Title X. Several comments expressed a belief that the proposed rule will result in negative health outcomes. A small number of comments raised concern that the proposed rule will result in a decrease in quality of care and would cost more to implement compared to the 2019 rule.

The Department also received several comments that were not relevant to the 2021 rule. These included several comments expressing opposition to the use of hormone therapy for adolescents, a few comments requesting that the Department include specific services within Title X that are already included in Title X (e.g., STI testing, cervical cancer prevention and treatment), and several personal testimonials either for or against family planning in general, but not specific to the 2021 rule.

*Response:* The Department agrees with the comments in support of the proposed rule and disagrees with the comments opposed to the proposed rule. The Department believes that the negative public health consequences of the 2019 rule are clear. As stated in the Background section, the 2019 rule dramatically reduced access to essential family planning and preventive health services for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created

to serve. The 2019 rule decreased the number of providers willing to participate in the Title X program, further reducing access to essential family planning services within states and communities across the country. The 2019 rule shifted Title X away from its history of providing client-centered, quality family planning services and instead set limits on the patient-provider relationship and the information that could be provided to the patient by the provider. The 2019 rule resulted in increased costs for grantee reporting that are unnecessary for ensuring grantee compliance. The Department believes that continued enforcement of the 2019 rule raises the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations with fewer opportunities for care are relegated to inferior access.

The Department will continue to enforce and monitor grantee compliance with all Title X statutory requirements and legislative mandates. The Department disagrees with comments that it is necessary to include language repeating the legislative mandates within the regulation itself. As noted above with respect to Section II. C. *Grantee and Subrecipient Compliance*, OPA explicitly states in NOFOs that all grantees must comply with the Title X statute, regulations, and legislative mandates, and applicants certify in the application materials that they will comply with federal law; compliance with program statutes and appropriations act requirements is also included as a standard term of the Title X grant award. Therefore, during the application process as well as by accepting funds, grantees have assured their compliance to the statute, regulations, and legislative mandates. Furthermore, OPA includes the legislative mandates in its grantee orientation and trainings and regularly monitors grantee compliance with the legislative mandates through grantee reporting and compliance monitoring visits.

The Department believes that the adoption of the 2021 proposed rule (86 FR 19812, April 15, 2021), with minor modifications discussed in this rule, will result in increased access to equitable, affordable, client-centered, quality family planning services. This will result in improved outcomes for all clients served by Title X. Additionally, the 2021 rule will ensure that the predominantly low-income clients who rely on Title X services as their usual source of medical care have access to

the same quality healthcare, including full medical information and referrals, that higher-income clients and clients with private insurance are able to access.

Comments Regarding Proposed Revisions and Technical Corrections to the 2000 Regulation

#### § 59.2. Definitions

In the NPRM, the Department proposed revising section 59.2 of the 2000 regulations by adding several new and modified definitions. The NPRM included a new definition of family planning services consistent with the definition included in QFP. The NPRM also included a new definition of service site consistent with the previous Title X Family Planning Guidelines that implemented the 2000 regulations, the 2014 *Program Requirements for Title X Funded Family Planning Projects* ("2014 Title X Program Requirements"). Finally, the NPRM included new definitions for adolescent-friendly health services, client-centered care, culturally and linguistically appropriate services, health equity, inclusivity, quality healthcare, and trauma-informed services. All new definitions included in the NPRM were taken from federal government agencies or major medical associations. The NPRM also retained definitions from the 2000 regulation for the following terms: Act, family, low-income, non-profit, Secretary, and state.

*Comments:* The Department received numerous comments in support of the new or revised definitions in the NPRM. Many comments expressed strong general support for the newly-proposed definitions, including definitions for client-centered care, cultural and linguistic appropriateness, family planning services, health equity, inclusivity, and trauma-informed. Numerous comments stated that "the proposed rule's definitions help to illustrate key aspects of quality care" and that "defining how services should be provided is an important step toward a more equitable Title X program." Numerous comments expressed specific support for the emphasis on health equity in the proposed rule. Comments expressed that the "added definition for health equity underscores the goal of ensuring that all Title X patients have the opportunity to attain their full health potential." Many comments also expressed support for the definition of family planning services, and specifically the inclusion of "FDA-approved" contraceptive products and reinstatement of the term "medically approved" to the definition. Several comments were supportive of not



including women whose employers do not cover contraception for religious reasons in the definition of low-income. One comment expressed support for the NPRM's "returned focus on Title X's priority population—low-income clients—and removal of the 2019 rule's re-definition of 'low income' to use the program to pay for contraceptive services for any people whose employers refuse to include coverage for such services in their employer sponsored insurance due to religious or moral objections." Several comments also expressed support for using more inclusive terminology throughout the NPRM and expressed that "'client' is more reflective of the diverse population of patients served by the Title X program."

Several comments, while supportive of the definitions included in the NPRM, did request specific revisions to many of the new or revised definitions. Several comments requested that the Department explicitly include systemic racism within the definition of health equity. Another comment requested that the Department revise the definition of health equity by expanding "the umbrella term 'socially determined circumstances' to 'other circumstances that are socially, economically, demographically, or geographically determined.'" One comment requested that the Department revise the definition of adolescent-friendly services to include "developmentally appropriate services that support the healthy cognitive, physical, sexual, and psychosocial development of adolescents as they transition from childhood to adulthood and account for their unique needs, including with respect to confidentiality, legal status, and autonomy." Other comments asked the Department to revise the definition of inclusivity to include non-religious people and the intersex community. One comment requested that the definition of trauma-informed care be revised to prevent future discrimination of transgender people by "clarifying that a trauma-informed program should not result in discrimination against any population."

The Department also received several comments opposing the new or revised definitions. A few comments opposed the definition of client-centered care and felt that it raised conscience concerns. Other comments opposed the definition of family planning services and specifically opposed removing abstinence and preconception health from the definition. One comment opposed the definition and said that "medically approved" did not include natural family planning. Another

comment questioned why the definition of family planning services did not emphasize "supporting unexpected pregnancies with assistance required by families and mothers—including emotional, educational, financial, and healthcare supports." Other comments expressed general opposition to the definition of family planning services and felt that the definition included abortion and abortion-related services.

One comment stated that the definition of health equity was vague and undermined the priority for serving low-income clients. Another comment stated that the focus on health equity was "targeting minority communities to restrict pregnancy," and another stated that the focus on equity was unnecessary because of protections already included in the Constitution. One comment opposed the definition of cultural and linguistically appropriate services and expressed that "the phrase 'culturally and linguistically appropriate services' may bless health practices, based on cultural norms, that lead to negative health outcomes." One comment opposed the definition of "trauma-informed" and said it was vague and that it was not clear what was required to be trauma-informed.

One comment opposed the definition of inclusivity and felt that it would drive faith-based providers out of the program. Another comment took issue with the definition of "inclusivity" and stated that "segregation or prioritization of Title X services by protected classes such as race violates the Constitution and several civil rights laws." A few comments opposed the use of the word "client" instead of "woman" throughout the NPRM and felt that the change in language was a disservice to women. Two comments opposed removing women who cannot receive contraception from their employer because they have a religious or moral objection from the definition of low-income. A few comments opposed the definition of quality healthcare. One comment opposed including client-centered and equitable within the definition of quality. Still another comment stressed that improving the quality of healthcare is a "dynamic process" and that "this dynamism requires a nimbleness often unattainable by national requirements." The commenter requested that the definition of quality be amended to allow "maximum flexibility at the state and local level to establish standards of care."

*Response:* The Department appreciates the supportive comments regarding the new and revised definitions in the NPRM and believes

that clear definitions for terms used throughout the regulations are important for consistent implementation. The Department acknowledges comments requested revisions to many of the definitions; however, the Department believes that it is important to use widely accepted and commonly used definitions from other federal agencies and national medical organizations as the foundation for the regulation. For this reason, the Department will not revise the proposed definitions as requested by several comments.

The Department disagrees that the definition of client-centered care raises conscience concerns. The purpose of the rule and the definitions is to refocus the program as a client-centered one, where well-being of the patient, not the provider, is the primary goal. As stated earlier, providers may avail themselves of existing conscience protections and file complaints with OCR, which will be evaluated on a case-by-case basis as is done with other complaints.

The Department also disagrees with comments objecting to the definition of family planning services. The definition of family planning services within the NPRM is consistent with the definition of family planning services in QFP. Contrary to some of the comments opposed to the definition of family planning services, the definition does include preconception health, natural family planning, and abstinence (as a component of natural family planning). Family planning services include a broad range of services related to achieving pregnancy, preventing pregnancy, and assisting clients in achieving their desired number and spacing of children. Also, given that the focus of Title X is on helping clients achieve pregnancy, prevent pregnancy, and achieve their desired number and spacing of children, the Department responds to comments requesting that Title X provide support to clients once they become pregnant by noting that this is beyond the scope of the Title X program. Further, as is clear from section 1008 of the Title X statute, none of the funds appropriated for Title X are used in programs where abortion is a method of family planning. No court has found the decades-long practice of referral upon request to violate that prohibition.

The Department disagrees with comments expressing concern with the definitions of health equity, cultural and linguistic appropriateness, inclusive, low-income, quality, and trauma-informed. The definitions proposed in the NPRM are widely used definitions from other federal agencies and major

medical organizations. The Department also disagrees that the definition of inclusive will drive faith-based organizations out of Title X or that it will segregate services; rather, the goal is to ensure that all people can actively participate in and benefit from family planning services. Finally, the Department disagrees with comments opposing the use of the word “client” and believes that it is important that the words used in Title X fully reflect the diversity of Title X clients.

In conclusion, the Department adopts the definitions from the NPRM for this provision as final with one revision and one technical correction. Given the revisions described later to 59.5(b)(1) and 59.5(b)(6) to include reference to “clinical services providers” in the regulatory text, the Department is adding a definition for “clinical services provider” to the final rule in 59.2. The definition of clinical services provider comes from OPA’s FPAR and has been widely used as a definition for Title X grantees to guide their FPAR data collection and reporting. As taken from FPAR, a clinical services provider is defined as “physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.”

One technical correction in the final rule is to the definition of family planning services. The definition in the NPRM stated, “Family planning services include a broad range of medically approved contraceptive services, which includes Food and Drug Administration (FDA)-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.” Since the FDA does not approve contraceptive “services,” but rather approves, clears, and authorizes (for purposes of this rulemaking, “FDA-approved”) “contraceptive products,” the definition in the final 2021 rule is revised. The final definition will now read, “Family planning services include a broad range of medically approved services, which includes FDA-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling,

assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.”

In addition to this revised definition for family planning services, the definitions from the NPRM for Act, adolescent-friendly health services, client-centered care, culturally and linguistically appropriate services, family, health equity, low-income, inclusive, non-profit, quality healthcare, Secretary, service site, state, and trauma-informed are all adopted as final.

*§ 59.5(a)(1). Broad Range of Acceptable and Effective Medically Approved Family Planning Methods and Services*

In the NPRM, the Department proposed revising section 59.5(a)(1) of the 2000 regulation to require sites that do not offer the broad range of methods on-site to provide clients with a referral to a provider who does offer the client’s method of choice. In addition, the NPRM specified that the referral must “not unduly limit the client’s access to their method of choice.” The complete NPRM language for this provision stated, “Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a referral to the client’s method of choice and the referral must not unduly limit the client’s access to their method of choice.” The proposed revisions recognized that while an organization that offers only a single method of family planning may participate as part of a Title X project, as long as the entire project offers the broad range of methods and services, offering only a single method of family planning could impact client access.

*Comments:* The Department received many comments in support of section 59.5(a)(1), especially in support of the requirement that Title X projects provide a broad range of acceptable and effective medically approved family

planning methods. Many comments expressed support for reinstating the term “medically approved” to the provision. Several comments requested that the Department add more specificity to the regulations to further define what is meant by “a broad range of methods.” One comment requested that the Department “expect Title X agencies to offer ‘many’ or ‘almost all of the most commonly used’ methods, and use referrals as an option of last resort.” Another comment requested the Department to “require each site to have at least one type of each provider-administered method in stock, and to have a process in place to offer other methods of contraception by prescription if not stocked in the clinic.”

The Department also received many comments expressing concern about allowing an organization to participate as part of a Title X project if it only offers a single method of family planning, as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Several comments expressed concern that “allowing Title X sites to offer a single method of contraception conflicts with Quality Family Planning standards and HHS’ stated goals regarding quality, client-centered care, and health equity.” Several other comments requested that “if HHS continues to allow specific sites to offer a single method of contraception, HHS must clarify that the method be medically approved and effective.”

The Department received further comments regarding the language in the NPRM requiring sites that do not offer the broad range of methods and services to “provide a referral, and the referral must not unduly limit the client’s access to their method of choice.” Many comments expressed support for requiring that sites refer clients if the site does not offer the client’s method of choice. Some comments expressed concern that it was unclear what was meant by “not unduly limit the client’s access” and how the requirement would be enforced across diverse communities. Some comments expressed concern that rural communities with more limited access to refer clients to other organizations nearby would be penalized if the referral was considered to unduly limit the client’s access. Some comments asserted that requiring referrals for a client’s method of choice would result in faith-based and natural family planning providers leaving the Title X network. Several other comments expressed concern that the referral requirement was “vague and

does not go far enough.” One comment asked the Department to “clearly outline the reasons and/or circumstances under which a Title X site may be excused from offering a broad range of medically approved methods and parameters, including a maximum ‘reasonable’ distance a Title X patient would have to travel to get their method of choice.” Another comment asked the Department to closely monitor the accessibility of referrals made by Title X sites. Other comments asked the Department to provide a specific number of minutes or miles from the Title X project to the referral location and to require that referrals be only to another Title X site to ensure the same discounted services would be available.

*Response:* The Department appreciates the supportive comments for this provision in the 2021 rule. Since acceptable and effective medically approved family planning methods can change over time, the Department does not believe that additional specificity regarding what is meant by a broad range of methods and services is necessary within the regulatory text. Instead, the Department will provide additional guidance and technical assistance to assist grantees in complying with the regulation and ensuring access to a broad range of acceptable and effective methods and services across their service sites.

The Department acknowledges the comments expressing concern with allowing an organization to participate in a Title X project if it only offers a single method of family planning as long as the overall project offers the broad range of methods and services. For much of the Title X program’s history, including in the 2000 regulations, the regulation has included this provision. The Department believes that retaining this provision in the 2021 rule is important to ensure flexibility in addressing community needs and recognizes that not all Title X service sites may be able to provide access to all methods and services. The Department will monitor and provide technical assistance to ensure that each grantee provides access to the broad range of acceptable and effective medically approved family planning methods and services to their clients.

The Department disagrees that the referral requirement will result in faith-based and natural family planning providers leaving the Title X network. This is in part based on our longstanding experience with the program which for decades has included faith-based and natural family planning providers. The requirement for referral is intended to support

continuity of care for Title X clients. There are any number of opportunities by which this requirement could be fulfilled including directly by the clinic site or by the grantee in instances when a provider objects or lacks capacity to fulfill this requirement. An array of providers, including those that only offer a single method on-site, have successfully participated in the Title X program for decades. The Department will monitor and provide technical assistance to ensure that supporting client access to requested methods and services does not violate federal conscience laws. As part of the statutory mandate, Title X projects must provide natural family planning services, and the program will work with projects to ensure they provide all statutorily required services. Again, the Department is emphasizing in this final rule the importance of ensuring access to client-centered care. Client-centered care is defined as being respectful of, and responsive to, individual client preferences, needs, and values, and ensuring that client values guide all clinical decisions. With an emphasis on providing services that are client-centered, the default should be the fullest provision of information and services to clients.

The Department understands, based on the comments received, that it is challenging to include within the regulation a requirement that sites must provide a referral that does “not unduly limit the client’s access.” The Department fully recognizes that the referrals available to each Title X site will differ depending on what other referral resources are available within or near the community. Some communities may have access to a wide range of providers to refer clients to within the same community, while other sites may need to refer clients to organizations located farther away. Given the challenges in having one standard definition for what is considered undue burden across all Title X sites, the Department has decided to revise section 59.5(a)(1) to remove the requirement that “the referral must not unduly limit the client’s access to their method of choice.”

In addition to the revision to remove this requirement, the final rule will also include one technical correction for this provision. The Department recognizes that if a Title X site does not have the client’s method of choice available on-site, the provider may be able to provide the client with a prescription for their method of choice, rather than having to provide a referral to another provider. To better account for this, the final provision will now require sites that are

unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services to provide a prescription to the client for their method of choice or referrals, as requested. As a point-of-entry to care, Title X sites often have robust referral networks with other safety-net agencies that are attuned to the needs of the client populations that they serve. While a prescription or referral does not guarantee a client the same schedule of discounts as at a Title X site, experience suggests that the family planning safety net recognizes and takes steps to limit accessibility burdens, including financial constraints, for the clients they serve. In addition, the Department will provide additional guidance and technical assistance to grantees to help them promote accessibility and limit patient burden.

With the revisions noted above, the revised language for the 2021 rule for 59.5(a)(1) is, “Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals, as requested.” This revised language is adopted as final.

*§ 59.5(a)(3). Services are Client-Centered, Culturally and Linguistically Appropriate, Inclusive, and Trauma-Informed; Protect the Dignity of the Individual; and Ensure Equitable and Quality Service Delivery Consistent With Nationally Recognized Standards of Care*

In the NPRM, the Department proposed revising section 59.5(a)(3) of the 2000 regulations. In addition to providing services that protect the dignity of the individual as required in the 2000 regulations, the NPRM stated, “Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the



dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.” These revisions were aimed at increasing access and ensuring equity in all services provided, which the Department believes is especially important for the Title X program with a statutory priority on serving low-income clients. In addition, the Department believes that the revisions will result in improved services for clients.

*Comments:* The Department received numerous comments in support of this revised provision. Many comments expressed full support for the provision and urged the Department to adopt it as quickly as possible. Others expressed specific support for the requirement that services be client-centered: “We support that the proposed rule names the importance of using client-centered models of care.” Still others expressed specific support for the inclusion of QFP within the 2021 rule and the requirement that Title X services be consistent with nationally recognized standards of care. One comment said, “[T]he Proposed Rule will again base the standards of care for the Title X program on the QFP guidelines and require that Title X clients receive high-quality, client-centered care that includes comprehensive, medically accurate counseling and information, and referrals for any other services sought.”

The Department received a few comments opposed to this provision. One comment felt that requiring services to be client-centered, inclusive, and trauma-informed would create additional “burden on applicants and providers to ensure equity within their programs.” Another comment argued with the definition of client-centered care and believed that it violated conscience protections. Still another expressed concern that the requirement for equity in conjunction with the requirement for inclusivity would violate civil rights laws and the Constitution “by giving certain classes of people preferential treatment.”

*Response:* The Department appreciates the comments in support of this provision and agrees that providing services in a manner required by this provision will advance equity, increase access, improve outcomes for Title X clients, and reinforce the longstanding requirement that “[s]ervices must be provided in a manner which protects the dignity of the individual.” The Department disagrees that the requirements of this provision will result in additional burden for applicants or providers, rather the

requirements of this provision simply ensure that all Title X services are of the highest quality and align with nationally recognized standards of care. The Department also disagrees that the requirements of this provision violate conscience protections and provides a specific response to comments concerning conscience earlier in Section II. *D. Application of Conscience Statutes in Title X.* Finally, the requirements of this provision do not give preferential treatment to any clients, but rather aim to ensure that all people can actively participate in and benefit from family planning services. In conclusion, the Department adopts the language from the NPRM for § 59.5(a)(3) as final without revisions.

*§ 59.5(a)(4). Services Do Not Discriminate Against any Client Based on Religion, Race, Color, National Origin, Disability, Age, Sex, Sexual Orientation, Gender Identity, Sex Characteristics, Number of Pregnancies, or Marital Status*

The NPRM proposed the same regulatory text for this provision as has been included in the 2000 regulations, which read “Provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.”

*Comments:* The Department received several comments regarding this provision and specifically expressing concerns with the phrase “without regard of.” Several comments expressed concern with the specific phrase and stated that “if Title X providers are intended, as stated in the proposed rule, to work towards advancing health equity, it is imperative that care is delivered in a way that intentionally centers and considers the identity and needs of the patient.” Several comments requested that the Department revise the provision to instead say “provide services in a manner that does not discriminate against any patient based on religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status” which they felt better supports health equity.

*Response:* The Department agrees with the comments and believes that revising the language as requested more clearly meets the intent of this provision, which is to prevent discrimination in the provision of services.

In addition, the Department is updating “sex” in 59.5(a)(4) to include sexual orientation, gender identity, and sex characteristics consistent with the section 1557 of the Affordable Care Act, case law, Executive Order 13988 (86 FR 7023, Jan. 25, 2021), and Departmental

policy (<https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html>). In *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), the U.S. Supreme Court held that Title VII of the Civil Rights Act of 1964 prohibition on employment discrimination based on sex encompasses discrimination based on sexual orientation and gender identity. Courts have now begun consistently interpreting similar language—“because of sex”—in other statutes to encompass these protections. See *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 616–617 (4th Cir 2020) (relying on *Bostock* to interpret Title IX as prohibiting policy prohibiting transgender student from using bathroom consistent with his gender identity). Moreover, as the Department of Justice has recently emphasized “Discrimination against intersex individuals is similarly motivated by perceived differences between an individual’s specific sex characteristics and their sex category (either as identified at birth or some subsequent time) . . . it is impossible to discuss intersex status without also referring to sex.” Title IX (justice.gov). As a result of the case law and Administration policy, the Department adds “sexual orientation”, “gender identity”, and “sex characteristics” to 59.5(a)(4).<sup>11</sup> The revised language for the 2021 rule for 59.5(a)(4) is “Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.” This revised language is adopted as final.

*§ 59.5(a)(8). Charges for Services With a Schedule of Discounts*

In the NPRM, the Department proposed revising section 59.5(a)(8) of the 2000 regulations by including widely accepted billing practices from the 2014 Title X Program Requirements. The NPRM text reads, “Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C.

<sup>11</sup> This language reflects requirements on Title X projects principally engaged in healthcare activities under 42 CFR part 59. If grants for the production of informational materials were again to be made under PHSA § 1005, this definition might not apply.

9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (i) Family income should be assessed before determining whether copayments or additional fees are charged. (ii) With regard to insured clients, clients whose family income is at or below 250 percent FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.”

*Comments:* The Department received several comments on this provision specifically seeking closer alignment of HRSA’s (Health Resources & Service Administration) Health Center Program (authorized by Section 330 of the PHS Act) and OPA’s Title X Program to minimize administrative burden for dually funded grantees. Specifically, one comment suggested modifying the proposed language in § 59.5(a)(8)(ii) to include additional language about sliding fee discounts from the Health Center Program Compliance Manual that states that sliding fee discounts are “subject to potential legal and contractual restrictions.” Another comment lauded § 59.5(a)(8)(ii) for ensuring that clients with family income at or below 250 percent FPL do not pay more than what they would otherwise pay under the schedule of discounts; however, the comment expressed that this “requirement violates insurance contracts and contradicts the guidance of other funders (e.g., HRSA).” Yet another comment expressed the need for additional guidance specific to Title X grantees and subrecipients operating under the Health Center Program, to assist with alignment of billing practices.

*Response:* The Department fully supports minimizing administrative burden for grantees funded under both the Title X program and HRSA’s Section 330 Health Center Program, recognizing that providers that dually participate in the two programs have been one of the fastest growing segments of the Title X provider network. Similar to the Health Center Program’s statutory requirement that health centers must operate in a manner such that no patient shall be denied service due to an individual’s inability to pay, the Department also believes, and the Title X statute requires, that an individual’s “economic status shall not be a deterrent to participation” in Title X program services. See PHS Act sec. 1006(c). The Department does not believe that adding to this rule the commenter’s suggested language with respect to the Health Center Program Compliance Manual is warranted as it is taken out of context

and does not state the statutory requirement. The Department believes that adding language requested in the comments could hinder Title X clients who qualify for sliding fee discounts from receiving the discounts, which is contrary to Title X’s mandate of prioritizing services to low-income clients. Further, OPA clarifies how Title X grantees may remain in compliance with Title X Program requirements when integrating services with HRSA’s Health Center Program grantees and look-alikes in OPA Program Policy Notice: 2016–11: Integrating with Primary Care Providers.”

Rather than revising the regulation and risk Title X clients not receiving all discounts for which they qualify, OPA will continue to work closely with HRSA to ease administrative burden for grantees funded under both programs. The Department will provide additional guidance and technical assistance to dually funded grantees aimed at reducing administrative burden. In conclusion, the Department adopts the language from the NPRM for § 59.5(a)(8) as final without revisions.

*§ 59.5(a)(9). Reasonable Measures To Verify Client Income*

In the NPRM, the Department proposed adding a new section 59.5(a)(9) to include one requirement from the 2014 Title X Program Requirements that grantees take reasonable measures to verify client income, and a new requirement that grantees use client self-reported income if the income cannot be verified after reasonable attempts. The Department believes that these proposed revisions will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees.

The NPRM text reads, “Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client’s participation in another program may use those data rather than re-verify income or rely solely on clients’ self-report. If a client’s income cannot be verified after reasonable attempts to do so, charges are to be based on the client’s self-reported income.”

*Comments:* The Department received several comments supporting the use of self-reported income. Comments received from members of the House of Representatives stated, “[W]e support the Department’s stance that patients be allowed to self-report their income, removing an unnecessary potential barrier to care.” Other comments

expressed support that “cost should not be a barrier” to receiving services. Still other reaffirmed support that allowing use of self-reported income “will greatly improve accessibility and affordability for low-income and uninsured patients seeking care from Title X program grantees.” One comment felt that the provision did not go far enough and asked that the language “explicitly state that a client’s self-reported income is sufficient, and that providers do not need to verify client income.”

The Department also received several comments on this provision specifically seeking closer alignment between Title X and HRSA’s Health Center Program (authorized by Section 330 of the PHS Act) to minimize administrative burden for dually funded grantees. Several comments felt that allowing a client’s self-reported income in cases where a client’s income cannot be verified despite reasonable attempts is inconsistent with the Health Center Program guidance. Comments reported that “health centers have broad discretion to determine the appropriate means to assess patient income and family size. While allowing self-declaration is typical in the health center program, some health centers have opted to adopt a policy establishing that self-declaration, without supporting documentation, is not an acceptable means to verify income for every patient.”

*Response:* The Department appreciates the supportive comments and agrees that the requirements in this provision will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees. The elimination of barriers to Title X services for low-income clients is important to the Title X program. The Department disagrees that the requirements in 59.5(a)(9) are not compatible with HRSA’s guidance. HRSA requires health centers to operate in a manner such that no patient shall be denied service due to an individual’s inability to pay; further, HRSA Health Center Program grantees are required to establish systems for sliding fee scale eligibility that comply with statutory requirements under section 330 of the PHS Act and regulatory requirements under 42 CFR 51c.303(f) and 56.303(f), which do not preclude self-declaration of income and family size. The Department believes that the HRSA Health Center Program requirements are fully consistent with the language in § 59.5(a)(9). A strict standard of income verification at a particular health center is a choice that does not warrant weakening a standard in Title X that the

Department has created to support and reinforce the program's statutory obligation to prioritize services to persons from low-income families. In conclusion, the Department adopts the language from the NPRM for § 59.5(a)(9) as final without revisions.

*§ 59.5(a)(12). State Reporting Laws*

In the NPRM, the Department proposed adding 59.5(a)(12) to retain some, but not all, language from the 2019 rule on notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. The NPRM language stated, "Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws"). Title X projects must provide appropriate documentation or other assurance satisfactory to the Secretary that it: (i) Has in place and implements a plan to comply with State notification laws. (ii) Provides timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or for providers with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws."

*Comments:* Many comments supported the elimination of section 59.17 from the 2019 rule. Comments supported eliminating "the 2019 rule's attempt to give HHS substantial oversight over compliance with complex state reporting requirements." Many comments noted that "professionals providing services in Title X-funded sites are aware of their reporting obligations, already receive training on them, and make reports in compliance with these requirements." Other comments stressed that determining compliance with state reporting laws lies with state authorities and noted that state reporting laws "are complex and vary widely from state to state."

One comment written in opposition to the NPRM expressed that the NPRM excluded "the mandatory reporting of sex trafficking and violence by intimate partners." Another comment requested that the 2019 Title X requirement for mandatory reporting be kept fully intact.

Another comment expressed concern that the proposed rule did not include the minor age record-keeping requirements and made an assertion that "[t]his lack of record keeping serves to enable sex traffickers and abusers to continue undetected in their abuse." The comment proposed reinstatement of these requirements and further proposed rescinding the funding of any grant recipient who fails to screen for and report sexual abuse or sex trafficking.

*Response:* The Department agrees with comments that all Title X recipients must follow state reporting laws and must comply with mandatory reporting requirements regarding child abuse, child molestation, sexual abuse, rape, or incest. The Department disagrees with the assertion that "... lack of record keeping serves to enable sex traffickers and abusers to continue undetected in their abuse." States have already established specific guidelines on the details that must be included in mandatory reports. As such, the Department believes that it is not necessary to impose this additional reporting burden through Title X regulations.

Since 1999, Congress has required, through the annual appropriations bill that, "[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest." All requirements in the appropriations riders are legislative mandates for the Title X program and all Title X grantees must comply with them. The Department will continue to enforce and monitor grantee compliance with all Title X statutory requirements and legislative mandates, including the mandate that "no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest."

As noted above with respect to Section II. C. *Grantee and Subrecipient Compliance*, OPA explicitly states in NOFOs that all Title X grantees must comply with the Title X statute, regulations, and legislative mandates. In addition, Title X applicants certify in the application materials that they will comply with federal law, and compliance with federal law, and compliance with program statutes and appropriations act requirements is also included as a standard term of the Title X grant award. Therefore, during the application process as well as by accepting funds, grantees have assured

their compliance to the statute, regulations, and legislative mandates. Furthermore, OPA includes the legislative mandates in its grantee orientation and trainings and regularly monitors grantee compliance with the legislative mandates through grantee reporting and compliance monitoring visits. OPA has consistently documented compliance with this mandated requirement and will continue to do so. A 2005 OIG report (OEI-02-03-00530) found that OPA has informed and periodically reminded Title X grantees of their responsibilities regarding state child-abuse and sexual-abuse reporting requirements.

Given the comments received and that Title X compliance with state mandatory reporting is already required through a legislative mandate for the Title X program, the Department does not deem it necessary to include this provision within the final regulation itself. Furthermore, this provision was a part of the 2019 rule that is being rescinded as a whole because it was a set of interrelated requirements that did not promote the public health or solve any Title X compliance concerns. In conclusion, the Department removes language from the NPRM for § 59.5(a)(12) from the 2021 final rule.

*§ 59.5(a)(13). Subrecipient Monitoring*

In the NPRM, the Department proposed adding 59.5(a)(13) to retain some, but not all, of the language from the 2019 rule related to subrecipient monitoring and reporting. This addition required Title X grantees to report on the subrecipients and referral agencies involved in their Title X projects and to provide their plan for oversight and monitoring of their subrecipients in grantee reports.

The NPRM language stated, "Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports: (i) Subrecipients and agencies or individuals providing referral services and the services to be provided; (ii) Description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and (iii) Explanation of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients."

*Comments:* The Department received several comments expressing concerns with the requirements of this provision and the high reporting burden associated with it. One comment requested that section § 59.5(a)(13) be



removed completely because of the additional reporting requirements it creates. Another comment requested that the Department only require grantees to submit the additional information required by this provision for subrecipients during regular reports but not during the initial application. The comment expressed a concern that for large Title X networks, “providing a description of all referral agencies and individuals, and outlining collaborations with each subrecipient, will still pose a significant burden for Title X grantees, particularly at the time of application when applicants are often afforded 60 days or less to apply.” Many other comments requested that the Department revise the language in this provision to focus only on subrecipients and not referral agencies “due to high burden” of reporting given the size of grantee networks and the high number of possible referrals made by individual sites. One comment stressed that “under the 2000 regulations, past grantees were required to monitor each organization and ensure that their clinic sites had appropriate referrals, that they were available to all clinic personnel, and that clients’ medical charts reflected appropriate referrals given and follow-up performed. However, grantees were not required to gather every referral source and report this information to HHS. This requirement will likely create an administrative burden that could be accomplished through HHS monitoring of grantees.”

*Response:* It is clear from the comments received that the proposed requirements in § 59.5(a)(13) are unnecessarily burdensome for grantees and will result in Title X staff having to spend valuable time on administrative reporting that could otherwise be spent providing services to clients. The Department agrees that monitoring how grantees are involving and monitoring their subrecipients in their project and the composition of grantee referral networks can be achieved through the Department’s existing grantee compliance monitoring system. Departmental grants regulations at 45 CFR 75.352 already document the requirements for pass-through entities and specify the reporting required of grantees for all pass-through entities. Furthermore, this provision was a part of the 2019 rule that is being rescinded as a whole because it was a set of interrelated requirements that did not promote the public health or solve any Title X compliance concerns.

Given the challenges noted with this provision and the additional reporting burden it would place on grantees, the

Department has decided to remove § 59.5(a)(13) from the 2021 final rule.

*§ 59.5(b)(1) Provide Medical Services Related to Family Planning*

In the NPRM, the Department proposed revising section 59.5(b)(1) of the 2000 regulations to acknowledge that consultation for medical services related to family planning can be provided by healthcare providers beyond the physician. Specifically, the NPRM stated, “Provide for medical services related to family planning (including consultation by a healthcare provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.” The proposed revision acknowledged that consultation for healthcare services related to family planning may be by a physician, but may also be by other healthcare providers, specifically acknowledging participation by physician assistants and nurse practitioners.

*Comments:* The Department received numerous comments supporting this revised provision, specifically in support of the recognition that a broad range of healthcare providers, in addition to physicians, have an important role to play in providing medical services related to family planning. Comments expressed agreement that “other clinicians often play an important role in providing family planning counseling and other services.” In addition, numerous comments asked the Department to clarify that this provision includes a broader range of healthcare providers beyond just physician assistants and nurse practitioners, as noted in the preamble of the NPRM. One comment asked that the Department use the definition of Clinical Services Provider from FPAR. Many other comments stated that “it is important to note that ‘consultation by a [healthcare] provider’ is not and should not be limited only to the examples cited by HHS, as these CSPs represent only one facet of healthcare providers in Title X settings.”

In addition to the numerous comments related to the array of healthcare professionals that are responsible for clinical service provision in Title X, the Department also received numerous comments asking for the language of this provision to be revised to clearly reflect telehealth as an acceptable service delivery modality. Several comments expressed

the importance of telehealth, especially throughout the COVID-19 pandemic, in allowing many Title X clients to continue to safely access essential services. Many comments expressed concern with the Department’s use of the word “telemedicine” in the NPRM instead of “telehealth” and felt that telehealth refers “to a broader scope of remote healthcare services than telemedicine and includes non-clinical services like counseling and education.” Several comments specifically asked the Department to revise § 59.5(b)(1) to be clear within the regulation that family planning services can be provided “in person or via telehealth.” Other comments asked the Department to specify within the regulation that telehealth services can include “audio-only modalities” and expressed that “all forms of telehealth modalities, including audio-only must be covered to remove any barriers of access for patients.” One comment asked the Department to provide guidance to Title X grantees on how to use telehealth services to ensure access, equity, and quality.

*Response:* The Department appreciates the comments in support of this provision, especially those that recognize the role of a broader range of healthcare providers in delivering family planning services. It was never the Department’s intention to imply that the only healthcare providers who could provide consultation under this provision were physician assistants and nurse practitioners. Physician assistants and nurse practitioners were included in the NPRM preamble to provide examples, but not to be exclusionary. The Department agrees with comments recommending use of the definition of Clinical Services Providers from FPAR to determine who is eligible as a healthcare provider under this provision and, as noted in the discussion related to Section 59.2 *Definitions*, is adding this definition to the final rule. The FPAR definition for Clinical Services Providers includes “physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.”

The Department agrees with the comments reiterating the importance of telehealth and the role of telehealth services in expanding access to services and advancing equity. The Department had always intended for the final rule to apply to family planning services

provided in-person or via telehealth and had specifically stated in the NPRM that the Department was “readopting the 2000 regulations with revisions that will enhance the Title X program and its family planning services, including family planning services provided using telemedicine, for the future.” Telehealth has played a critical role for Title X in responding to the COVID-19 pandemic. By utilizing telehealth modalities, Title X grantees were able to continue to provide essential family planning services throughout the pandemic. With the onset of COVID-19, the vast majority of Title X grantees transitioned to some form of telehealth service delivery in order to continue providing services while limiting contact between individuals and protecting client safety. Telehealth was commonly used by Title X grantees for non-urgent visits that did not require a physical exam. Of importance, more than half of the grantees that were able to deliver telehealth during COVID-19 reported to OPA in their progress reports that they intended to continue offering telehealth services even after the pandemic ends, due to the advantages for both clients and staff.

Given the comments received, the Department believes that it is important to include language specifically in the regulatory text to clarify that telehealth services also constitute appropriate service delivery. The Department also agrees with the request to use the term “telehealth” rather than “telemedicine” to be clear that telehealth services include non-clinical services like counseling and education. While cognizant that synchronous telehealth services may be delivered through different modes of technology and that audio-only modalities may mitigate access barriers, particularly for those with limited internet and/or cellular data, the Department does not agree that the regulatory text needs to be so specific to reference the use of “audio-only modalities,” especially given how rapidly technology can change. Instead, the Department will provide additional training and technical assistance to grantees on the use of various telehealth modalities to improve access, quality, and equity.

With the revisions noted above, the revised language of 59.5(b)(1) for the 2021 rule is, “Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically

indicated, and provide for the effective usage of contraceptive devices and practices.” This revised language for § 59.5(b)(1) is adopted as final.

*§ 59.5(b)(3) Community Education, Participation, and Engagement*

In the NPRM, the Department proposed revising section 59.5(b)(3) of the 2000 regulations to reflect the desire to engage diverse individuals to make services accessible. Specifically, the NPRM stated, “Provide for opportunities for community education, participation, and engagement to: (i) Achieve community understanding of the objectives of the program; (ii) Inform the community of the availability of services; and (iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.” The revision added language to clarify the intent to engage diverse individuals to ensure access to equitable, affordable, client-centered, quality family planning services.

*Comments:* The Department received one comment expressing support for 59.5(b)(3), especially emphasizing the importance of the participation and engagement of diverse individuals in making family planning services accessible, equitable, and client-centered. The Department received one comment asking that the language of 59.5(b)(3) be revised to “be clear that the needs of adolescents and young adults” are included in community education, participation, and engagement.

*Response:* The Department appreciates the comments in response to this provision. Community education, participation, and engagement are important for Title X projects because they help ensure that the community is aware of the Title X program and the services available. In addition, community participation and engagement are critical to helping Title X providers better understand and center the needs and experiences of the community and the clients served. Together, community education, participation, and engagement are foundational for ensuring access, equity, and quality through the provision of Title X services.

In response to the one comment requesting a revision to the provision, the Department believes that the proposed regulatory text is broad and already includes the needs of adolescents and young adults as currently written. The Department does not believe that additional revisions are needed to the regulatory text in order to

respond to the comment received. In conclusion, the Department adopts the language from the NPRM for § 59.5(b)(3) as final without revisions.

*59.5(b)(6) Services Under Direction of Clinical Services Provider*

The NPRM proposed the same regulatory text for this provision as has been included in the 2000 regulations, which read, “Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.”

*Comments:* The Department received numerous comments requesting revisions to the regulatory text for this provision. Comments requested that the regulation expand beyond physician-only directed services. Several comments requested that the text be revised to be consistent with the revisions to § 59.5(b)(1), which recognized the importance of a broader range of healthcare providers, in addition to physicians, in providing family planning services. Several comments requested revisions to expand direction of family planning services to very specific types of healthcare providers. One comment asked that the language clarify that nurse practitioners have the authority to direct family planning programs. Another comment asked that the language be revised from physician to “licensed healthcare provider.” Still another asked that this section be revised to specifically authorize physician assistants to direct family planning services.

Several other comments were specific to advanced practice registered nurses (APRNs) and asked that the language specify that APRNs “be able to serve as the medical director (in states with full practice authority).” One commenter pointed out that “while state licensure rules vary, many states have granted full practice authority to APRNs, enabling independent practice.” Another comment requested that the Department consider whether registered nurses could direct family planning services “especially in areas of provider shortage.” A final comment asked for the text to be amended to allow services provided “under the direction of an advanced practice clinician, if the services offered are within their scope of practice and if allowable under state law.”

*Response:* Given the comments received, the Department agrees that having consistency between 59.5(b)(1) and 59.5(b)(6) is important to more clearly reflect the role of a broader range of healthcare providers in providing

Title X services. The Department also agrees with comments that other healthcare providers, including physician assistants and APRNs in many states, have authority to direct family planning programs and should be included within the regulation.

As stated earlier, the Department received comments in response to 59.5(b)(1) asking for more clarity on the term “healthcare providers” included in the NPRM, with many comments recommending use of the term “clinical services provider” as defined by OPA in FPAR. As a result, the Department has revised the final language for 59.5(b)(1) to use the term “clinical services provider” instead of “healthcare provider” and has revised 59.2 to include the FPAR definition of “clinical services provider” in the regulatory text. The FPAR definition for clinical services provider includes “physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care.”

To ensure consistency between 59.5(b)(1) and 59.5(b)(6) as requested in the public comments, the Department has revised the language for the 2021 rule for 59.5(b)(6) to, “Provide that family planning medical services will be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.” This revised language for § 59.5(b)(6) is adopted as final.

#### *59.5(b)(8) Coordination and Use of Referrals and Linkages*

In the NPRM, the Department proposed revising section 59.5(b)(8) of the 2000 regulations to add language to include primary healthcare providers in the list of referrals and to state that referrals are to be to providers in close proximity to the Title X site when feasible. The NPRM stated, “Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.”

*Comments:* The Department received several comments expressing support

for revising the provision to include primary healthcare providers in the list of referrals and to require that referrals be to nearby providers, when feasible. One comment expressed support and said that “referring Title X patients to local primary care physicians would facilitate access to continuous, comprehensive healthcare.” Several other comments expressed support and stressed the existing collaborative relationships between many HRSA-funded health centers and Title X sites. Comments expressed that “referral relationships allow the health center and the Title X site to become more familiar with one another’s operations and service lines, often serving as a useful precursor to a more integral relationship in the future.”

*Response:* The Department appreciates the many supportive comments in response to this revised provision. The Department agrees that it is important for Title X clinics to provide referrals and linkages to a wide range of healthcare services to help facilitate access for Title X clients to needed healthcare services beyond family planning. Given that the Department received no comments expressing concern with or opposition to the proposed modification, the Department adopts the language from the NPRM for § 59.5(b)(8) as final without revisions.

#### *§ 59.6 Suitability of Informational and Educational Material*

In the NPRM, the Department proposed revising the 2000 regulations by combining requirements specific to the Information and Education Advisory Committee (“Advisory Committee”) that were in sections 59.5(a)(11) and 59.6 and consolidating all of the Advisory Committee information in one place, under section 59.6. The NPRM proposed several revisions to 59.6 to clarify that the regulation applies to both print and electronic materials (in both the title of the section and regulatory text), that the upper limit on council members should be determined by the grantee, that the factors to be considered for broad representation on the Advisory Committee match the definition of inclusivity earlier in the regulation, and that materials will be reviewed for medical accuracy, cultural and linguistic appropriateness, and inclusivity and to ensure they are trauma-informed.

Specifically, the NPRM states:

“(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials

(print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) Size. The Committee shall consist of no fewer than five members and up to as many members as the recipient determines, except that this provision may be waived by the Secretary for good cause shown.

(2) Composition. The Committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).

(3) Function. In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(ii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed;

(iii) Determine whether the material is suitable for the population or community to which is to be made available; and

(iv) Establish a written record of its determinations.”

*Comments:* The Department received one comment in support of the proposed revisions that expressed that “this will ensure that information and materials provided to clients are appropriate and suitable for the specific communities to be served.” Another



comment shared specific support for the requirement that grantees provide “culturally and linguistically appropriate” materials. One comment opposed to this provision expressed that the language in 59.6 “remains overly narrow and prescriptive” and recommended that the language be revised to require “a Community Advisory Board charged with a broad array of responsibilities to ensure the appropriateness of Title X services for intended communities.” Another comment opposed “underrepresented communities” in composition of the advisory council and claimed that “to the extent it results in segregation or prioritization of Title X services or committee membership by protected classes such as race, it violates the Constitution and several civil rights laws.” This same comment also opposed having the advisory committee review materials to certify that they are trauma-informed and inclusive.

*Response:* The Department appreciates the supportive comment in response to this provision. The role of the Advisory Committee is critically important to ensure that the information and educational materials provided to Title X clients are factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed. Engaging the community and population served in the Advisory Committee itself is a key strategy to inform the grantee about the needs and experiences of the community and population served, and to make sure that the information and education materials are appropriate for the community and population served.

The Department disagrees with the comment that the language in 59.6 is too narrow and prescriptive. The Department believes that the requirements set forth in 59.6 are critical for ensuring that informational and educational materials provided to Title X clients are factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma-informed. In addition, the Title X statute prescribes requirements related to the informational and educational materials developed or made available under the project, including that they “will be suitable for the purposes of [Title X] and for the population or community to which they are to be made available, taking into account educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials” (PHS Act sec. 1006(d)(1)), and also prescribes requirements related

to the Advisory Committee, including that the “committee shall include individuals broadly representative of the population or community to which the materials are to be made available” (PHS Act sec. 1006(d)(2)).

The Department also disagrees with the comment that the regulation is segregating or prioritizing services or committee members. The text of the provision calls for the Committee membership to include “individuals broadly representative of the population or community for which the materials are intended..... Including but not limited to individuals who belong to underserved communities.” Since all communities served are different, the aim of this provision is to ensure the committee is representative of the community and population served, as required by the statute. The Department disagrees with the opposition to having the Advisory Committee review materials to ensure they are inclusive and trauma-informed. Providing information and educational materials that are inclusive and trauma-informed are a critical component of providing quality, client-centered care.

The Department does not believe that revisions are needed to the regulatory text included in the NPRM. As a result, the Department adopts the language from the NPRM for § 59.6 as final with a technical correction to include “sex characteristics”.

#### § 59.7 Grant Review Criteria

In the NPRM, the Department proposed revising section 59.7 of the 2000 regulations to add one additional review criterion that the Department may consider in deciding which family planning projects to fund and in what amount, which is “the ability of the applicant to advance health equity.” Adding this new criterion to the 2000 regulations brings the total number of grant review criteria specified in the regulation from seven to eight. Advancing health equity is critical to the mission of the Title X program. The addition of this grant review criterion will help ensure that grant funds are awarded to those applicants who are best able to help the Department in achieving the goal of advancing health equity through the Title X program.

*Comments:* The Department received several comments in response to this revised provision asking for additional details in future funding opportunities about what the new criterion means and how it will be measured. One comment provided specific examples of how the Department could operationalize the new grant review criterion. Another comment asked the Department to

“develop additional guidance and tools that Title X sites and other healthcare organizations can readily implement” to meaningfully advance health equity. Still another comment expressed concern that the NPRM did not include an explanation “for how a Title X project can, in fact, ensure equity in general and specifically in a way that does not lead to actual discrimination based on a protected basis.”

*Response:* The Department appreciates the comments and recommendations received. The grant review criteria from the 2000 regulation include several criteria aimed at assessing the need, capacity, and ability of the applicant organization, including the relative need of the applicant, the capacity of the applicant to make rapid and effective use of the federal assistance, the adequacy of the applicant’s facilities and staff, the relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project, and the degree to which the project plan adequately provides for the requirements set forth in these regulations. In addition, the grant review criteria from the 2000 regulation include two criteria aimed at assessing need in the communities served, including the number of clients, and, in particular, the number of low-income clients to be served; and the extent to which family planning services are needed locally.

The Department believes that adding the new grant review criterion to assess the ability of the applicant to advance health equity is important to enable OPA to more fully assess the extent to which the applicant’s project will promote health equity through the Title X services provided. Under 59.2, health equity is defined as “when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.”

Adding a focus on advancing health equity will not lead to discrimination or preferential treatment as expressed by some comments opposed to the NPRM. Rather, including a focus on advancing health equity aims to ensure that all people can actively participate in and benefit from family planning services. By advancing equity across the federal government, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone. The federal government’s goal in advancing equity is to provide everyone

with the opportunity to reach their full potential.

To measure the ability of an applicant to advance health equity, OPA could assess how the location of planned Title X service sites compares to the need for family planning services within the communities served. OPA also could assess how the applicant plans to provide services in a manner that is culturally and linguistically appropriate. OPA could assess how the project plans to monitor outcomes by clients' income, race, ethnicity, geographic location, etc., as well as how the project plans to address differences in outcomes through the Title X services provided. OPA could also ask applicants to describe the uptake of services by client demographics to identify existing disparities and to describe how they would work to reduce existing disparities in service provision. In addition, some agencies within the Department have incorporated disparity impact statements as a part of the post-grant award process. Disparity impact statements are just one example of a tool that OPA may consider in order to measure demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities. These are just examples of how this new grant review criterion could be operationalized within future NOFOs.

The Department will provide details on how all grant review criteria will be measured in future NOFOs, including the new grant review criterion on advancing health equity. The Department also plans to develop training and technical assistance products to assist family planning providers in advancing health equity.

In conclusion, the Department adopts the language from the NPRM for § 59.7 as final with one technical correction to replace "his estimate" with "an estimate" to reflect inclusive language.

#### § 59.10. Confidentiality

In the NPRM, the Department proposed revising the provision of the 2000 regulations related to confidentiality, which was section 59.11 in the 2000 regulations, but is now section 59.10, to add a widely accepted practice in the Title X community, indicating that reasonable efforts must be made to collect charges without jeopardizing client confidentiality. In addition, the Department proposed adding a requirement that grantees must inform the client of any potential for disclosure of their confidential health

information to policyholders where the policyholder is someone other than the client. Since state and local laws may vary across jurisdictions (e.g., some are likely to result in notification to the policyholder that the client has received services, others provide for an "opt out" process whereby the client can elect that such a notification will not be made), this addition was added to ensure that the client understands the implications for using their insurance and the options available for them to maintain confidentiality.

Specifically, the NPRM stated, "All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client."

*Comments:* The Department received numerous comments in support of this provision and the proposed revisions. Many comments expressed support for restoring "the confidentiality protections that have been a hallmark of the Title X program." Several comments expressed support for allowing "providers to return to the high standard of confidentiality that all patients, including adolescents, deserve when accessing healthcare services, especially ones as potentially sensitive as family planning and sexual health." Several comments also specifically supported the new language on potential disclosure to policyholders.

The Department also received numerous comments requesting further revisions to the regulatory text for 59.10. Numerous comments urged the Department to add language to the regulatory text to clarify that "Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services."

Comments underscored that this language has been longstanding guidance from OPA for the Title X

program and is included in *OPA Program Policy Notice 2014-01: Confidential Services to Adolescents*. One comment stated, "We encourage you to take all possible steps when finalizing the rule to ensure that adolescents are treated with the same client-centered approach as all other patients at Title X-funded health centers." In addition, many comments generally opposed the removal of language from the regulation that encouraged family participation in the decision of a minor patient to seek family planning services and requested that the language be added back into the final regulation.

Several other comments expressed concern with a new rule from the HHS Office of the National Coordinator for Health Information Technology (ONC) about Electronic Health Records and information blocking. Several comments requested that the Department confirm in the final rule that withholding of sensitive information in compliance with 59.10 would "fall within the ONC rule's privacy exception and would not constitute information blocking."

*Response:* The Department appreciates the comments in support of the revised provision in the NPRM. The Department agrees with comments to add specific language to the final rule regarding adolescent confidentiality to reflect Title X legal requirements. Since 1981, the Title X statute has required that, "to the extent practical, [grantees] shall encourage family participation" in Title X projects. 42 U.S.C. 300(a). However, such involvement is not mandatory and grantees are required to protect clients' confidentiality. Specifically with respect to adolescents, courts have for decades recognized minors' rights to receive confidential services under the Title X program. See, e.g., *Planned Parenthood Federation of America, Inc. v. Heckler*, 712 F.2d 650 (D.C. Cir., 1983) (Title X expressly protects minors' rights to seek services confidentially). See also *OPA Program Policy Notice 2014-01: Confidential Services to Adolescents*.

The Department does not agree that specific language needs to be added to the final rule to clarify the applicability of the ONC rule to Title X. Instead, as described below related to section 59.12, OPA suggests that grantees seek guidance from ONC with respect to the applicability of the information-blocking provision, as ONC administers this rule and, thus, would be in the best position to interpret it. With this revision, the final language in the 2021 rule for 59.10 is, "(a) All information as to personal facts and circumstances obtained by the project staff about

individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.

(b) To the extent practical, Title X projects shall encourage family participation.<sup>12</sup> However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

This revised language for § 59.10 is adopted as final.

#### § 59.12 Other Applicable Regulations

In the NPRM, the Department included the same regulatory text as had been included in section 59.10 of the 2000 regulations, which is a list of additional HHS regulations that apply to the Title X family planning services program. The NPRM proposed a technical correction to update the list of applicable regulations by adding 45 CFR part 87.

*Comments:* Many comments that generally support the rule disagree with the proposed technical correction to section 59.12, which includes a reference to 45 CFR part 87 ("Equal Treatment for Faith-based Organizations") in the list of regulations that apply to the Title X program. Such comments argued that this rule does not apply to Title X because the previous administration explicitly declined to apply this rule to Title X in the faith-based organizations rule issued on December 17, 2020 (*see* 85 FR 82037, 82117). Additionally, these comments argued that 45 CFR part 87 does not apply to the Title X program because it is a health services program, and 45 CFR part 87 only applies to social services programs; thus, the reference to this regulation should be removed from

section 59.12 of the final rule. Other comments argued that, if the Department is planning to make technical corrections to update the list of regulations that apply to the Title X program, it should take the opportunity to clarify the applicability of 45 CFR part 92 ("Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Programs or Activities Administered by the Department of Health and Human Services Under Title I of the Patient Protection and Affordable Care Act or by Entities Established Under Such Title") as well as the statute under which it was authorized, section 1557 of the Affordable Care Act. These comments stipulated that if the Department makes changes to this regulation in the future, section 59.12 should be updated at that time to include 45 CFR part 92 on this list of applicable regulations.

Comments opposing the rule agreed with the inclusion of 45 CFR part 87 in section 59.12, but questioned why the Department did not include an explanation for deleting references to the now-superseded 45 CFR part 92 ("Uniform administrative requirements for grants and cooperative agreements to state and local governments"). These comments also argued that the Department should include a reference to 45 CFR 88 ("Protecting Statutory Conscience Rights in Health Care; Delegations of Authority") on the list of applicable regulations, as it will apply to the Title X program once related litigation is resolved.

*Response:* The Department appreciates the comments addressing the proposed technical corrections to 45 CFR 59.12, but has decided to eliminate that section from the final rule in its entirety. Since the regulations that apply to the Title X program will apply of their own accord, whether or not they are cross-referenced in 42 CFR part 59, subpart A, the Department has concluded that the list of applicable regulations in 59.12 serves no useful purpose and, in contrast, may be misleading. The Department is concerned that since regulations are amended frequently, any current listing of applicable regulations could soon become outdated. Additionally, while all of the longstanding Departmental regulations, such as those prohibiting discrimination, still apply, the Department is concerned that the 59.12 list may provide a false impression that only the regulations included in this section apply to the Title X program. The Department believes that Title X

grantees can more accurately assess which regulations apply to the Title X program by reviewing the regulations at issue and, in some instances, seeking guidance from the agencies which administer them. For example, several comments, in the context of addressing the confidentiality provisions, questioned the applicability of the information-blocking provisions in the "21st Century Cures Act:

Interoperability, Information Blocking, and the ONC Health IT Certification Program" rule (85 FR 25642, May 1, 2020). As that rule is administered by the HHS Office of the National Coordinator for Health Information Technology (ONC), ONC would be in the best position to interpret that rule.

Most importantly, OPA provides information to Title X grantees regarding which regulations apply to their Title X programs and is committed to providing ongoing guidance and assistance as questions arise. OPA includes information about applicable regulations in grant documents, such as NOFOs and Notices of Award, and in technical assistance webinars. Given that grantees can receive accurate and up-to-date information from OPA about which regulations apply to their Title X programs, the Department has decided to delete section 59.12 from the final rule.

### III. Regulatory Impact Analysis

#### A. Introduction

The Department has examined the impact of the final rule under Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, Executive Order 13132 on Federalism, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct the Department to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Department believes that this final rule is not an economically significant regulatory action as defined by Executive Order 12866 because it will not result in annual effects in excess of \$100 million.

The Regulatory Flexibility Act requires the Department to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule will lessen

<sup>12</sup> 42 U.S.C. 300(a) states: "To the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection."



administrative burdens for grantees of all sizes. Therefore, the Secretary certifies that the final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 605.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires the Department to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications. The final rule will not have a significant impact on state funds as, by law, project grants must be funded with at least 90 percent federal funds. 42 U.S.C. 300a-4(a). The Department has determined that this final rule does not impose such costs or have any federalism implications. The Department expects that while some states may not support the policies contained in this final rule, many states and local health departments will support the policies contained in this final rule, and that it will increase participation by states (many of which withdrew as a result of the 2019 rule).

#### *B. Summary of Costs, Benefits and Transfers*

This final rule will revise the regulations that govern the Title X family planning services program by revoking the 2019 rule and readopting the 2000 regulations with several modifications. This approach will allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

We predict that this final rule will increase the number of grantees receiving Title X funds. In turn, the additional service sites supported by funding will result in additional clients served under the program. These clients receive access to contraception, and

public health screening including clinical breast exams, Papanicolaou (Pap) testing, and testing for STIs. These services result in improved family planning and birth spacing, earlier detection of breast and cervical cancer, and earlier detection of sexually transmitted infections including chlamydia, gonorrhea, syphilis, and human immunodeficiency virus (HIV), all of which correlate to net savings for the government. This screening and testing can result in significant cost savings from earlier treatment and other interventions. This final rule will also increase the diversity of grantees receiving funds, including geographic diversity to states that do not currently have a Title X grantee.

The final rule will also focus grantees on providing services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery. This focus is especially important for the Title X program that prioritizes services for low-income clients.

This regulatory impact analysis reports the activity occurring at Title X-funded sites to provide policymakers with this information. However, the direct impact within the program does not account for services that continue to be provided at sites not receiving Title X funding, filling the gap left by providers that withdrew from the program following the restrictions placed on funding included in the 2019 rule.

#### *C. Comments on the Preliminary Economic Analysis and Our Responses*

On April 15, 2021, the Department issued a proposed rule to revise regulations relating to the Title X program. The Department prepared a preliminary regulatory impact analysis (PRIA) for the proposed rule. Many comments were outside the scope of this rule. The paragraphs below describe and respond to the comments received on the PRIA.

#### *Summary of comments addressing the PRIA that were generally opposed to the rulemaking:*

Several of the comments suggested that the Department used flawed data in its forecasts or failed to account for COVID-19 in the PRIA. Several of the comments suggested that the Department does not have data to assess the effect of the 2019 rule, arguing that COVID-19 is a complicating factor. Several comments noted that clients served under the Title X program declined between 2009 and 2018, suggesting long-term trends can account

for some of the reduction in clients served under the 2019 rule. Other comments noted that long-term demographics trends are responsible for the decline in services, such as rise in median household income, rise in individuals with private insurance, and more diverse options available in the healthcare market.

Several of the comments suggested that grantees withdrawing from the program may not have resulted in a decline in services, and that some services were continued with state and private funds. Several comments pointed out that some states saw an increase in clients after the 2019 rule. One comment argued that, when one of two Ohio grantees left the program, the remaining grantee prevented a gap in coverage.

#### *Responses to comments addressing the PRIA that were generally opposed to the rulemaking:*

The primary estimate of the baseline Title X service grantees, subrecipients, service sites, and clients served are derived from calendar year 2019 figures, which predate COVID-19. The PRIA's estimate of the likely effect of the proposed rule is to gradually return to the level of grantees, subrecipients, service sites, and clients that the program supported in calendar years 2016 to 2018, which also predates COVID-19. COVID-19 may complicate attempts to precisely estimate the magnitude of the effect of the 2019 rule on the Title X program, but pre-pandemic data from calendar year 2019 preceding COVID-19 reveals a significant drop-off in grantees, subrecipients, service sites, and clients supported by the program, which are contrary to the predictions in the 2019 rule.<sup>13</sup> The Department acknowledges the uncertainty in the forecast of the baseline scenario of no regulatory action by including a sensitivity analysis in the PRIA. The upper-bound forecast of 3,095,666 clients served annually by the Title X program under the baseline scenario of the 2019 rule is well below the approximately 4 million clients served during calendar years 2016 to 2018.

The Department disagrees with the suggestion that long-term trends drove the reduction in clients served under the 2019 rule. Between calendar years

<sup>13</sup> If adjustment to the requirements of the 2019 rule took time for grantees and prospective new grantees (and possibly continues to do so), then immediate post-issuance difficulties in obligating Title X funds could ease over the years, which would in turn lead to a trend back toward pre-2019 Title X service levels even in the analytic baseline. However, the effects of the COVID-19 pandemic would obscure, in the available data, whether such trends are present or absent.

2009 and 2014, the number of clients reported served by the Title X program declined from 5.2 million to 4.1 million, with an average annual decline in clients served by about 211 thousand per year. Between calendar years 2014 and 2018, the number of clients served fell more gradually, with an average annual decline in clients served of about 48 thousand per year. In calendar year 2019, the number of clients served fell by about 844 thousand. The Department believes it is appropriate to attribute the bulk of the reduction in clients served during calendar year 2019 to the 2019 rule.

The Department agrees with the comments that state and private funding likely averted some of the public health consequences that would have otherwise occurred in the immediate time period following implementation of the 2019 rule. The Department acknowledged this limitation in the PRIA and noted that one effect of the proposed rule would be “transfers (for example, if Title X newly funds medical services that would, in the absence of the proposed rule, be provided by charitable organizations or other private payers).” The Department noted that several states contributed emergency or one-time funds. It is not clear whether state or private funding will be available for the full-time horizon of the analysis, which begins in calendar year 2022.

While the PRIA reported that “seven states (CO, DE, KY, ND, NM, NV, TX) experienced an increase in the number of Title X *clinics* after the 2019 regulatory change,” this observation is different than the claim about increases in *clients*. Colorado, Delaware, Kentucky, North Dakota, New Mexico, and Texas all saw declines in the number of female users served in 2019 and 2020 compared to 2018 (male users saw declines as well). Nevada increased the number of female users from 9,236 in 2018 to 11,156 in 2019, and again to 11,190 in 2020. The specific claim about Ohio cannot be supported with the available data. Ohio Title X grant recipients reported 83,497 female clients served in 2018, dropping to 68,669 in 2019, and dropping further still to 27,322 in 2020. Similarly, given the implementation of the 2019 rule occurred midway through the calendar year, the 2019 data likely mask the full negative impact of the 2019 rule that year.

*Summary of comments addressing the PRIA that were generally supportive of the rulemaking:*

Several comments agreed with the observation in the PRIA that the 2019 rule resulted in a reduction in grantees and clients served under the Title X

program. Several comments gave examples of states or other entities that saw a decrease in clients served. Several comments discussed the disproportionate impact the 2019 rule had on low-income individuals, individuals in rural communities, people of color, and other populations. Several comments discussed the impact of the 2019 rule on the quality of family planning services outside the Title X program, as well as the financial impact on clients receiving services outside the Title X program. Several comments argued that other sources of funding besides the Title X program, including state funding, would not be reliable sources of funding in the future.

*Responses to comments addressing the PRIA that were generally supportive of the rulemaking:*

The Department appreciates the specific examples provided in comments and agrees with the assessment that the 2019 rule resulted in a reduction in grantees and clients served at the national level, and that these effects were more pronounced in certain regions, communities, and demographic groups. The PRIA concluded, and this regulatory impact analysis affirms, that this rulemaking will likely result in an increase in clients served within the Title X program compared to a baseline of no further regulatory action. The Department also maintains the finding in the Further Discussion of Distributional Effects Section in the PRIA in this analysis that the effects of this final rule will accrue approximately in proportion with income and race and ethnicity figures typically served by the Title X program.

The Department agrees that services provided outside the Title X program were not always identical to Title X-funded services. While some providers were able to provide reproductive health services in the absence of Title X funding, comments disclose that they were not providing the same services provided in Title X program. Specifically, commenters suggested that services provided outside of the Title X program did not follow the same standards as in Title X, and that the schedule of discounts and subsidies were not applied as required in the Title X program.

The Department agrees with the comments that other sources of funding besides the Title X program may not be reliable sources of funding over calendar years 2022 through 2026, the time horizon of the PRIA and this final regulatory impact analysis. The Department has expanded the discussion of this point in the analysis.

Comments Received in Response to Executive Order 13132 Federalism Review

*Comment:* Several comments were critical of the Regulatory Impact Analysis, stating that it ignores the federalism implications of the proposed rule. These comments argued that the proposed rule compels states to adopt policies that conflict with their own laws, particularly with regard to subrecipient restrictions that several states have put in place, and other state-described “integrity requirements.” Additionally, several comments raised concerns that the Department did not extend the comment period to specifically study the federalism impacts. Other comments expressed a belief that the proposed rule would have no federalism effects as it is a discretionary grant program in which states can choose to participate or not.

*Response:* While the Department agrees that states have an interest in enforcement of their statutes, it believes that this final rule respects federalism, as it does not interfere with state laws. As noted previously, the Department has decided not to include a subrecipient nondiscrimination provision in the final rule at this time and, thus, concerns raised by these comments about harm to state program integrity requirements or a need to extend the deadline to assess the impact of this harm are now moot.

Additionally, while states are eligible to apply for Title X grants, the Title X statute was not enacted as a federal-state cooperative statute, as is made clear by the eligibility of nonprofit, private entities to apply for grants directly. And, since the Department is free to attach reasonable conditions to the awarding of funds to carry out best its statutory goals and these conditions only apply to the receipt of federal Title X funds, states that object to the rule requirements or believe that there is a conflict with state law priorities are free to opt out of the federal grant program. Thus, the final rule does not interfere with state laws or have federalism implications, as state laws are only implicated if those states with contrary state laws wish to apply for Title X funds.

#### *D. Summary of Changes*

The Department has revised the economic analysis of impacts to account for additional information, newer data, and in response to comments. Many of the estimates and Tables have been updated to account for minor revisions to the calendar year 2020 data. For example, Table D1 now identifies 75

Grantees, 867 Subrecipients, 3,031 Service Sites, and 1,536,743 Clients Served, compared to 73 Grantees, 803 Subrecipients, 2,682 Service Sites, and 1,536,744 Clients Served reported in the PRIA. These revised estimates carry through to other estimates and Tables.

As described in greater detail in the Preamble, the final rule adopts eight of the fourteen revisions initially proposed in the NPRM and nine of the ten technical corrections initially proposed in the NPRM as final without additional changes. Based on the comments received in response to the NPRM and a subsequent, new interpretation by the Department since the NPRM was issued, the final rule includes nine additional revisions and six additional technical corrections compared to what was proposed in the NPRM. This analysis has been updated to be consistent with these changes, but these changes do not substantially alter the estimates of the quantified economic impacts.

#### E. Final Economic Analysis of Impacts

##### a. Background

The Title X family planning program, administered by the U.S. Department of Health and Human Services (HHS), Office of Population Affairs (OPA), is the only federal program dedicated solely to supporting the delivery of family planning and related preventive healthcare. The program is designed to provide “a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)” with priority given to persons from low-income families. In addition to offering these methods and services on a voluntary and confidential basis, Title X-funded service sites provide

contraceptive education and counseling; breast and cervical cancer screening; STIs and HIV testing, referral, and prevention education; and pregnancy diagnosis and counseling. The program is implemented through competitively awarded grants to state and local public health departments and family planning, community health, and other private nonprofit agencies. In fiscal year 2021, the Title X program received approximately \$286.5 million in discretionary funding.<sup>14</sup>

On March 4, 2019, HHS published a final rule to “prohibit family planning projects from using Title X funds to encourage, promote, provide, refer for, or advocate for abortion as a method of family planning; require assurances of compliance; eliminate the requirement that Title X projects provide abortion counseling and referral; require physical and financial separation of Title X activities from those which are prohibited under section 1008; provide clarification on the appropriate use of funds in regard to the building of infrastructure, and require additional reporting burden from grantees.”

##### b. Market Failure or Social Purpose Requiring Federal Regulatory Action

The regulatory impact analysis associated with the 2019 rule predicted that the additional restrictions on grantees would result in “an expanded number of entities interested in participating in Title X.” Further, the analysis suggested the 2019 rule would result in “enhanced patient service and care.” Contrary to these predictions, during the initial period of the 2019 rule’s implementation, the policy appears to have had the opposite effect. As described in greater detail in the Baseline section, the restrictions

included in the 2019 rule are associated with a substantial reduction in the number of Title X grantees, subrecipients, and service sites, resulting in a corresponding reduction in total clients served. The Department is compelled to act quickly to ameliorate these negative consequences by promulgating this final rule since the Title X program serves a low-income population that is particularly vulnerable to losing access to these services. This final rule is needed to improve the functioning of government and the effectiveness of the Title X program.

##### c. Purpose of the Rule

This final rule will revise the regulations that govern the Title X family planning services program by revoking the 2019 rule and readopting the 2000 regulations with several modifications. This approach will allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

##### d. Baseline Conditions and Impacts Attributable to the Rule

The Department adopts a baseline that assumes the requirements of the 2019 rule remain in place over the period of our analysis. To characterize the real-world impact of the Title X program under this regulatory approach, the Department developed an annual forecast of grantees, subrecipients, service sites, and total clients served. The key inputs to the forecast are historical data on Title X service grantees. For calendar years 2016 to 2020, this information is summarized in the 2020 Title X Family Planning Annual Report.

TABLE D1—TITLE X SERVICE GRANTEES

Year	2016	2017	2018	2019	2020
Grantees .....	91	89	99	100	75
Subrecipients .....	1,117	1,091	1,128	1,060	867
Service Sites .....	3,898	3,858	3,954	3,825	3,031
Clients Served .....	4,007,552	4,004,246	3,939,749	3,095,666	1,536,743

Source: Title X Family Planning Annual Report, 2020: Exhibit A–2a.

The data for calendar years 2016–2019 included all grantees, subrecipients, and service sites operating at any time during the year. The implementation of the 2019 rule occurred mid-year in 2019. Following this regulation, 19 grantees, 231 subrecipients, and 945 service sites withdrew from the Title X program. The

reduced number of grantees, subrecipients, services sites, and clients served observed in 2019 and 2020 cannot be explained by a reduction in discretionary funding for the program, which has remained constant at \$286.5 million throughout this time period. Since the 2019 figure includes clients served by these service sites for more

than half of the year, adopting 3.1 million clients served as an annual forecast would likely overstate activity in the program under the current regulations. Indeed, preliminary figures for 2020 approximate that only 1.5 million clients were served. However, this figure likely represents an underestimate for a typical year of the

<sup>14</sup> Does not include supplemental funding.



program under the current regulations since services were likely disrupted by the ongoing public health emergency.

As the primary estimate, the Department adopts 2,512,066 clients served as the baseline annual impact of Title X under the policies of the 2019 rule. This 2.5 million-figure corresponds to the number of clients served in 2019 among remaining grantees as of March 2021. For comparison, this primary estimate represents a 37 percent reduction in clients served compared to the average of clients served from 2016 to 2018. In the Uncertainty and Sensitivity Analysis Section, the Department adopts the 1.5 million-client figure as a lower-bound estimate, and 3.1 million clients as an upper-bound estimate of the annual program impact under the baseline.

Table D2 summarizes the baseline forecast for the same categories of historical data presented in Table D1. The Department adopts the current count for grantees, subrecipients, and service sites and assumes constant funding and that these figures will be constant over the time horizon of this analysis.

TABLE D2—BASELINE FORECAST OF TITLE X SERVICES

Baseline forecast	Annual
Grantees .....	75
Subrecipients .....	867
Service Sites .....	3,031
Clients Served .....	2,512,066

In addition to the reduction in grantees, subrecipients, service sites, and total client served, the Department notes that six states currently have no Title X services, including HI, ME, OR, UT, VT, and WA. There are six additional states that have limited Title X services, including AK, CT, MA, MN, NH, and NY.<sup>15</sup>

In line with the reduction in clients served under the 2019 rule, data also reveal a significant drop in services provided. For example, when comparing 2019 figures to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008

fewer clients received intrauterine devices (IUDs). For oral contraceptives and IUDs, this was a 27 percent reduction, and for hormonal implants, a 21 percent reduction. These percentages are similar in magnitude to the 21 percent reduction in clients served in 2019 compared to 2018. Additionally, 90,386 and 188,920 fewer Pap tests and clinical breast exams, respectively, were performed in 2019 compared to 2018. Confidential HIV tests decreased by 276,109. Testing for STIs decreased by 256,523 for chlamydia, 625,802 for gonorrhea, and 77,524 for syphilis. Appendix A of the FPAR contains national annual trends for many of the services discussed above. The reductions in services reported in 2019 compared to 2018 represent the largest year-over-year reductions in services for each reported measure since at least 2014. Similar to the earlier discussion relating to long-term trends relating to clients, we attribute the bulk of the reductions to these services to the 2019 final rule.

For the forecast of services provided under the baseline scenario, the Department adopts the percentage of clients receiving each service in the 2019 Title X Family Planning Annual Report. For example, in 2019, about 23 percent of female clients received a clinical breast exam. The Department assumes the same share of clients will be served by Title X for screening and STI testing. Table D3 reports the best estimate of the annual services provided under the baseline scenario. These services are described in greater detail later in this Section.

TABLE D3—BASELINE TITLE X CANCER SCREENING AND SEXUALLY TRANSMITTED INFECTION TESTING

Year	Annual
Clinical Breast Exams .....	509,550
Pap Tests .....	443,087
Chlamydia Test .....	1,266,508
Gonorrhea Test .....	1,420,198
Syphilis Test .....	536,619

TABLE D3—BASELINE TITLE X CANCER SCREENING AND SEXUALLY TRANSMITTED INFECTION TESTING—Continued

Year	Annual
Confidential HIV Test .....	777,536

Source: Calculations based on Title X Family Planning Annual Report, 2019: Exhibits 26 and 29.

The Department predicts that the main effect of the final rule would be to return to Title X program impact levels observed prior to the 2019 rule. The estimates of the long-run equilibrium of grantees, subrecipients, service sites, and total clients served are informed by the data from 2016 to 2018, the last three years of data that are unaffected by the declines experienced following the 2019 rule. Specifically, the Department adopts the average across these three years as the long-run estimates. These averages are 93 grantees, 1,112 subrecipients, 3,903 service sites, and approximately 4.0 million clients served.

To complete the forecast of the policy scenario, the Department assumes that it will take two years for program participation and clients served to achieve the long-run equilibrium estimates. This two-year phase-in is consistent with a scenario in which most service sites that withdrew from the Title X program have remained open, with some operating at a lower capacity, than they did prior to the 2019 rule. It is also consistent with an expectation that many of the grantees and service sites that withdrew from the program would be able to rejoin if the NPRM issued on April 15, 2021, were finalized. In year one, following the effective date of the proposed rule, the number of clients served would increase to approximately 3.2 million. In year two, this number would increase again to approximately 4.0 million and remain constant for the duration of the analysis. These figures are presented in Table D4. The Department acknowledges uncertainty in this estimate and includes a discussion in the Uncertainty and Sensitivity Section, below.

TABLE D4—POLICY SCENARIO FORECAST OF TITLE X SERVICE GRANTEEES

Year	2022	2023	2024	2025	2026
Grantees .....	84	93	93	93	93
Subrecipients .....	990	1,112	1,112	1,112	1,112
Service Sites .....	3,467	3,903	3,903	3,903	3,903
Clients Served .....	3,247,958	3,983,849	3,983,849	3,983,849	3,983,849

<sup>15</sup> As noted earlier, seven states (CO, DE, KY, ND, NM, NV, TX) experienced a meaningful increase in

the number of Title X clinics after the 2019 regulatory change.

To characterize the effect of the final rule, the Departments compares the policy scenario forecast to the baseline forecast described in the previous section. Table D5 reports the difference between these two scenarios, which

represents the net effect of the proposed rule. For example, in year one after this rule is effective, the number of clients served would increase by approximately 736,000 as compared to the baseline scenario. Approximately 88 percent of

clients served in 2016 to 2018 are female, and the Department uses this percentage to estimate the increase in clients served by sex under the policy scenario.

TABLE D5—EFFECT OF THE PROPOSED RULE ON TITLE X SERVICES

Year	2022	2023	2024	2025	2026
Increase in Grantees .....	9	18	18	18	18
Increase in Subrecipients .....	123	245	245	245	245
Increase in Service Sites .....	436	872	872	872	872
Increase in Clients Served .....	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Female .....	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Male .....	86,896	173,791	173,791	173,791	173,791

Clients served under the Title X program experience outcomes that include reducing unintended pregnancy through greater access to contraception. The averted unintended pregnancies translate to a reduction in unplanned births, a reduction in abortions, and reduction in miscarriages. Also, Title X clients receive cancer screenings and testing for STIs. These screenings and testing can identify treatable conditions, improving the quality of life and extending the lives of beneficiaries. In the case of STIs, additional testing and corresponding earlier treatment can reduce the likelihood of worse health outcomes and future infertility resulting from those infections. This final rule will expand service to socioeconomically disadvantaged populations, most of whom are female,

low-income, and young. The Department discusses this in greater detail in the Section on Distributional Effects.

To further explore the likely effect of the Title X program on unintended pregnancy, we rely on existing methodology for estimating number of unintended pregnancies prevented each year among U.S. women who depend on publicly funded family planning services.<sup>16</sup> Among this subgroup of women who use any method of contraception, 46 in 1,000 women are expected to experience an unintended pregnancy. This figure can be compared to 296 unintended pregnancies per 1,000 women who are unable to access publicly funded family planning services. The Department applies this estimate of a reduction of 250 unintended pregnancies per 1,000

contraception clients to the number of additional female clients served under the Title X program who adopt any method of contraception.

For year one, the analysis reflects multiplying 735,892 clients by 88 percent to yield 648,996 female clients. Among female clients, approximately 14 percent indicate they are not using a method of contraception, according to figures in the 2019 Title X Family Planning Annual Report. The analysis reduces the potential number of clients that would potentially reduce the likelihood of an unintended pregnancy by 14 percent to yield 558,205 clients expected to benefit from a contraceptive method. Approximately 47 percent of unintended pregnancies result in births, 34 percent in abortion, and 19 percent in a miscarriage.<sup>17</sup>

TABLE D6—EFFECT OF THE PROPOSED RULE ON TITLE X-ASSOCIATED CONTRACEPTION

Year	2022	2023	2024	2025	2026
Clients Served .....	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Women Served .....	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Women Served Using Contraception .....	558,205	1,116,411	1,116,411	1,116,411	1,116,411

Unintended pregnancies increase the risk for poor maternal and infant outcomes. Women who give birth following an unintended pregnancy are less likely to have benefitted from preconception care, to have optimal spacing between births, and to have been aware of their pregnancy early on, which in turn makes it less likely that

they would have received prenatal care early in pregnancy.<sup>18 19</sup>

Title X funding recipients also perform preventive health services such as cervical and breast cancer screening, and testing for STIs, including chlamydia, gonorrhea, syphilis, and HIV. Table D7 presents the effect of the final rule on Title X-associated cervical and breast cancer screenings. These

figures are calculated by multiplying the number of additional women served by the program in each year by approximately 23 percent for clinical breast exams, of which five percent result in a referral for further evaluation; and 20 percent for Pap testing, of which 13 percent with a result of atypical squamous cells (ASC) that require further evaluation and possibly

<sup>16</sup> Jennifer J. Frost and Lawrence B. Finer (2017). Memo entitled "Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula." <https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf>. Accessed on March 14, 2021.

<sup>17</sup> Jennifer J. Frost, Lori F. Frohwirth, Nakeisha Blades, Mia R. Zolna, Ayana Douglas-Hall, and Jonathan Bearak (2017). "Publicly Funded Contraceptive Services at U.S. Clinics, 2015." [https://www.guttmacher.org/sites/default/files/report\\_pdf/publicly\\_funded\\_contraceptive\\_services\\_2015\\_3.pdf](https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf). Accessed on March 14, 2021.

<sup>18</sup> Jessica D. Gipson, Michael A. Koenig, and Michelle J. Hindin. "The Effects of Unintended

Pregnancy on Infant, Child, and Parental Health: A Review of the Literature." Studies in family planning 39.1 (2008): 18–38. Web.

<sup>19</sup> Power to Decide. Maternal and Infant Health and the Benefits of Birth Control in America. Accessed on March 8, 2020 from <https://powertochoose.org/sites/default/files/resources/supporting-materials/getting-the-facts-straight-chapter-3-maternal-infant-health.pdf>.

treatment, and one percent of which have a high-grade squamous intraepithelial lesion (HSIL) <sup>20</sup> or higher, indicating the presence of a more severe condition.

Clinical breast exams can identify patients requiring further evaluation of an abnormal finding. Pap tests (or pap smear tests) can detect precancers and cervical cancer cells and can also be tested for viral infections that can turn

into cervical cancer. At a population level, these screenings save lives by helping patients identify cancer earlier and by preventing other conditions from developing into cancer.

TABLE D7—EFFECT OF THE FINAL RULE ON TITLE X-ASSOCIATED CERVICAL AND BREAST CANCER SCREENING ACTIVITIES

Year	2022	2023	2024	2025	2026
Clinical Breast Exams .....	149,269	298,538	298,538	298,538	298,538
Referred .....	7,463	14,927	14,927	14,927	14,927
Pap Tests .....	129,799	259,598	259,598	259,598	259,598
Tests with ASC or higher .....	17,304	34,609	34,609	34,609	34,609
Tests with HSIL or higher .....	195	391	391	391	391

Table D8 presents the effect of the proposed rule on Title X-associated testing for STIs among female clients. These are calculated by adopting estimates that 49 percent of women are

tested for chlamydia, 55 percent for gonorrhea, 19 percent for syphilis, and 28 percent for HIV. Table D9 presents the same information for men. The share of male clients tested for these

infections are the following: 61 percent for chlamydia, 68 percent for gonorrhea, 39 percent for syphilis, and 53 percent for HIV.

TABLE D8—ADDITIONAL WOMEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia .....	318,008	636,016	636,016	636,016	636,016
Gonorrhea .....	356,948	713,895	713,895	713,895	713,895
Syphilis .....	123,309	246,618	246,618	246,618	246,618
Confidential HIV .....	181,719	363,438	363,438	363,438	363,438

TABLE D9—ADDITIONAL MEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia .....	53,006	106,013	106,013	106,013	106,013
Gonorrhea .....	59,089	118,178	118,178	118,178	118,178
Syphilis .....	33,889	67,779	67,779	67,779	67,779
Confidential HIV .....	46,055	92,109	92,109	92,109	92,109

Table D10 reports the additional total clients tested for STIs under Title X. These tests can identify treatable conditions that can cause discomfort, permanent damage to reproductive systems including infertility, and in certain cases, death. The 2019 Title X Family Planning Annual Report indicates confidential HIV testing identifies a positive case for

approximately 0.38 percent of all HIV tests performed. Under the final rule, testing under Title X is estimated to identify an additional 873 positive cases of HIV in the first year. In subsequent years, this estimate increases to 1,745. Testing for these STIs can also reduce the likelihood that an individual will spread an infection. In addition to testing, Title X-funded service sites also

provide HIV/AIDS prevention education. Pre-exposure prophylaxis (PrEP) has emerged as an effective HIV prevention strategy for individuals who are most at risk, and the inclusion of PrEP in the HIV prevention services provided at Title X sites is becoming an increasingly important method for protecting individuals of all ages from acquiring HIV.

TABLE D10—ADDITIONAL CLIENTS TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia .....	371,014	742,029	742,029	742,029	742,029
Gonorrhea .....	416,037	832,074	832,074	832,074	832,074
Syphilis .....	157,199	314,397	314,397	314,397	314,397
Confidential HIV .....	227,774	455,547	455,547	455,547	455,547
Positive Test Results .....	873	1,745	1,745	1,745	1,745

Additional services of the type provided under Title X will likely result

in reduced costs to taxpayers in line with a reduction in unintended

pregnancies, pre-term and low birth weight births, STIs, infertility, and

<sup>20</sup> HSIL is the abnormal growth of certain cells on the surface of the cervix.

cervical cancer. One report estimates that each dollar spent on these services results in a net government saving of \$7.09.<sup>21</sup> We do not replicate the calculations, but note that they are derived from cost savings associated with averting unintended pregnancy and complications such as pre-term and low birth weight births. These cost savings are also derived from detecting and treating STIs that would have resulted in more serious outcomes, including infertility, cancer, and death.

In addition to the effects described above, the final rule will also enhance the equity and dignity associated with access to family planning services provided by Title X. A recent research brief summarized interviews with 30 women sharing their experiences with contraceptive access, providing suggestive evidence that birth control has an important positive impact on women's lives. Interviewees noted that birth control allowed women to "to pursue academic and professional goals, achieve financial stability, and maintain their mental and physical health."<sup>22</sup> These recent interviews are consistent with the historical experience of the importance of birth control. For example, one econometric study identifies a causal relationship between the introduction and diffusion of the birth control pill and the increase in women enrolling in professional degree programs and increasing the age at first marriage.<sup>23</sup> As of a result of the Affordable Care Act's contraceptive coverage requirement, Title X can play a critical role, helping provide insured clients with access to contraception without cost-sharing alongside its longstanding role supporting contraceptive access without cost-sharing for Medicaid beneficiaries and those whose incomes are equal to or less than 100 percent of the federal poverty level (FPL), which allows these clients to experience these and other positive outcomes associated with access to contraception.

Researchers have identified other economic, social, and health impacts of increased access to family planning,

<sup>21</sup> Jennifer J. Frost, Adam Sonfield, Mia R. Zolna, and Lawrence B. Finer (2014). "Return on Investment: a fuller assessment of the benefits and costs of the US publicly funded family planning program." *Milbank Quarterly* 2014 Dec; 92(4): 696-749.

<sup>22</sup> Rebecca Peters, Sarah Benetar, Brigitte Courtot, and Sophia Yin (2019). "Birth Control is Transformative." Urban Institute. [https://www.urban.org/sites/default/files/publication/99912/birth\\_control\\_is\\_transformative\\_1.pdf](https://www.urban.org/sites/default/files/publication/99912/birth_control_is_transformative_1.pdf). Accessed April 6, 2021.

<sup>23</sup> Goldin, Claudia and Lawrence F. Katz (2002). "The power of the pill: Oral contraceptives and women's career and marriage decisions." *Journal of Political Economy* 110(4): 730-770.

contraception, and treatment. For example, Bailey et al. (2019) finds "that children born after the introduction of federal family planning programs were seven percent less likely to live in poverty and 12 percent less likely to live in households receiving public assistance." They perform an additional bounding analysis, which suggests that about two thirds of the estimated gains are due to increases in the incomes of parents.<sup>24</sup> A recent summary discusses other impacts of access to family planning services in the United States and in other countries, which extends beyond women and girls, to their children and wider communities.<sup>25</sup>

The tables above present observable metrics of the effect of the Title X program, which is important for evaluating the direct effect of the program. For this reason, the scope of the analysis initially focuses on clients served and services provided by Title X-funded sites. To properly account for the net effect of the final rule when comparing the baseline scenario to the policy scenario, the Department would need to assess the extent to which clients and services continue to be provided through other channels than Title X-funded sites without the proposed rule. As a general matter, the impacts of this final rule may include:

- Transfers between grantees and prospective grantees within the Title X program;
- other transfers (for example, if Title X newly funds medical services that would, in the absence of the proposed rule, be provided by charitable organizations or other private payers); and
- societal benefits and costs to the extent that the volume or characteristics (such as location, which determines travel costs) of medical services would differ with and without the final rule.

As noted earlier in this preamble, all Planned Parenthood affiliates—which, in 2015, served 41 percent of all contraceptive clients at Title X-funded service sites—withdrawn from Title X, citing the 2019 rule. However, a comparison of Planned Parenthood's two most recent annual financial reports indicates no subsequent decrease in the number of patients served and an increase, from 9.8 million to 10.4 million, in the number of services

<sup>24</sup> Bailey, Martha J., Olga Malkova, Zoë M. McLaren (2019). "Does Access to Family Planning Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X." *Journal of Human Resources* 54:4 pp. 825-856. doi:10.3368/jhr.54.4.1216-8401R1.

<sup>25</sup> Emily Sohn (2020). "Strengthening society with contraception." *Nature* 588, S162-S164.

provided per annum (pre-pandemic).<sup>26</sup> Although such year-to-year comparisons are simplistic and a focus on just one organization (even a prominent one, with extensive activities) has obvious limitations, this evidence may suggest that the Title X program impacts quantified elsewhere in this regulatory impact analysis may largely be associated with transfers.

The Department received a number of public comments drawing connections between the short-term effects of the 2019 rule and long-term potential for a reduction in total family planning clients served, not limited to the Title X program. For example, two states (NY, WA) reported receiving emergency reserve funds through state funding in order to sustain the level of care that they provided under Title X; however, both noted that this funding is not reliable and sustainable from year to year. One grantee in Maine reported keeping all clinics open and operating with the use of the association's reserve funds and through private fundraising, which was an unsustainable and impractical task to continue. Another provider also reported fundraising to maintain care while also noting the administrative burden; however, many health centers were forced to close or reduce hours due to the lack of Title X funding. The same organization also reported the need to scale back or eliminate education and outreach programs in many states. These public comments suggest that the long-term effect of the 2019 rule would have been to reduce clients served and family planning services provided beyond the Title X program.

In addition to the effects on the quantity of services, several comments discussed the effects on the quality of services provided. One organization and the Attorneys General of 22 states and the District of Columbia noted that losing Title X providers had a negative effect on patients that sought care. They argued that it was more difficult for patients to obtain culturally competent care and that the requirements of the 2019 rule placed a burden on providers and their method of pregnancy counseling, as they were "inconsistent with the standards of care and required incomplete and confusing lists and referrals for pregnant clients." Finally, several states reported that while their efforts were refocused to recruiting and

<sup>26</sup> Please see [https://www.plannedparenthood.org/uploads/filer\\_public/2e/da/2eda3f50-82aa-4ddb-acce-c2854c4ea80b/2018-2019\\_annual\\_report.pdf](https://www.plannedparenthood.org/uploads/filer_public/2e/da/2eda3f50-82aa-4ddb-acce-c2854c4ea80b/2018-2019_annual_report.pdf) and [https://www.plannedparenthood.org/uploads/filer\\_public/67/30/67305ea1-8da2-4cee-9191-19228c1d6f70/210219-annual-report-2019-2020-web-final.pdf](https://www.plannedparenthood.org/uploads/filer_public/67/30/67305ea1-8da2-4cee-9191-19228c1d6f70/210219-annual-report-2019-2020-web-final.pdf).



onboarding new providers into their Title X network under the 2019 rule, they faced resistance or a lack of interest, and their provider networks did not increase under the 2019 rule, continuing to adversely impact the communities they serve.

These public comments suggest that the effects identified in this regulatory impact analysis for the time horizon covering calendar year 2022 through 2026 are unlikely to be limited to a reversal of what was observed immediately after issuance of the 2019 final rule. The Department acknowledges persistent challenges with clearly disaggregating the effects that represent transfers from effects that represent benefits and costs as a result of this final rule; however, it is important to reiterate that total Title X funding remained unchanged upon issuance of the 2019 final rule and will be unchanged as a result of this final rule, so while some entities receive less funding (and they and their clients experience regulation-induced ancillary harm, which can manifest itself in the quantity or quality of associated services), other entities receive more funding. The Department maintains the analytical approach of estimating the number of additional clients served and services provided under the Title X program under this final rule, while acknowledging challenges in quantitatively assessing whether this final rule will result in additional clients served and family planning services provided, not limited to the Title X program, as compared to the baseline of no further regulatory action. Despite such uncertainty, analysis based on evidence available at this time generally supports a conclusion that the projections accompanying the 2019 rule have not been borne out.

e. Further Discussion of Distributional Effects

The Title X program is designed to provide services with priority given to persons from low-income families. According to the 2019 figures, 64 percent of clients have income under 101% of the federal poverty level; 14 percent between 101 percent FPL and 150 percent FPL; seven percent between 151 percent FPL to 200 percent FPL; three percent between 201 percent FPL and 250 percent FPL; seven percent over 250 percent FPL; and five percent have an unknown or unreported income level. Among program clients, 33 percent self-identified as Hispanic or Latino of all races; three percent as Asian and Not Hispanic or Latino; 22 percent as Black or African American and Not Hispanic or Latino; 32 percent as White and Not Hispanic or Latino; five percent as Other or Unknown and Not Hispanic or Latino; and four percent are Unknown or Not Reported. Furthermore, Title X requires Title X projects to provide services for adolescents without required parental consent, thereby making Title X a critical source of sexual and reproductive healthcare for young people. In 2019, two percent of program clients were younger than 15, and eight percent were younger than 18. Additional information about the number and distribution of all family planning clients by age and year are available in Exhibit A-3a of the 2019 Family Planning Annual Report. The benefits of revoking the 2019 rule would likely accrue proportionally with these income and race and ethnicity figures. The costs of revoking the 2019 rule would likely accrue proportionally to the income and other demographics of the general public.

This final rule will also likely have important geographic effects. As described in greater detail in the

Baseline section, six states currently have no Title X services, and six additional states have limited Title X services. This final rule is expected to result in restoration of services to individuals in these states.

f. Uncertainty and Sensitivity Analysis

All of the major drivers of the quantified effects of this analysis are dependent on the forecast of the baseline number of clients served. The Department acknowledges the uncertainty in this baseline and has performed a sensitivity analysis to quantify its importance. For the primary baseline, the analysis uses 2.5 million annual clients of Title X services, which corresponds to the number of clients in calendar year 2019 among remaining grantees. For its sensitivity analysis, the Department investigates the effect of the proposed rule compared to a baseline with 1.5 million clients, corresponding to the estimates for 2020. For comparison, the analysis reviewed the effects using an upper bound of 3.1 million clients served, which is the reported figure for 2019, but which includes 19 grantees, 231 subrecipients, and 945 service sites that withdrew from the Title X program following the 2019 rule.

Table F1 presents the number of clients served under different assumptions of the baseline. The analysis also recalculates the number of clients served for the final rule scenario for each of the baseline assumptions. Since the number of clients served in the first year is the midpoint between the baseline and long-run equilibrium figure, the number of clients served in 2022 under the final rule is lower for the lower-bound scenario than the primary baseline. Similarly, the number of clients served under the final rule is higher in the upper-bound scenario.

TABLE F1—TITLE X CLIENTS SERVED UNDER DIFFERENT BASELINE ASSUMPTIONS

Year	Baseline	Baseline, LB	Baseline, UB	Proposed rule	Proposed rule, LB	Proposed rule, UB
2022 .....	2,512,066	1,536,743	3,095,666	3,247,958	2,760,296	3,539,758
2023 .....	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2024 .....	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2025 .....	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849
2026 .....	2,512,066	1,536,743	3,095,666	3,983,849	3,983,849	3,983,849

Table F2 calculates the effect of the final rule under different baseline assumptions. These estimates are reported by year, as well as in present value and annualized for the five-year time horizon of the analysis, applying a

three percent and a seven percent discount rate. Under the lower-bound baseline scenario, the final rule will have about a 66 percent greater impact on the number of clients served in annualized terms under the primary

baseline scenario. Under the upper-bound baseline scenario, the final rule will have approximately a 64 percent lesser impact.



TABLE F2—EFFECT OF THE PROPOSED RULE ON TITLE X CLIENTS UNDER DIFFERENT BASELINE ASSUMPTIONS

Year	Proposed rule	Proposed rule, LB	Proposed rule, UB
2022 .....	735,892	1,223,553	444,092
2023 .....	1,471,783	2,447,106	888,183
2024 .....	1,471,783	2,447,106	888,183
2025 .....	1,471,783	2,447,106	888,183
2026 .....	1,471,783	2,447,106	888,183
PDV, 3% .....	6,025,877	10,019,113	3,636,461
PDV, 7% .....	5,346,852	8,890,110	3,226,687
Annualized, 3% .....	1,315,778	2,187,719	794,038
Annualized, 7% .....	1,304,047	2,168,215	786,959

As discussed earlier, the Department acknowledges uncertainty in how quickly the Title X program will be able to restore service to levels experienced prior to the declines associated with the 2019 rule. The primary analysis adopts a two-year phase for grantees, subrecipients, service sites, and clients served to reach the long-run equilibrium estimates. If a large number of service

sites have shut down permanently, the assumption of a two-year phase-in would likely result in an overestimate of the final rule's effect over the time horizon of the analysis. Similarly, if a small number of service sites have shut down, the analysis would tend to underestimate the effect of the final rule. Therefore, as a second sensitivity analysis, the Department presents

estimates that adopt alternative assumptions about the length of time it will take to reach the long-run equilibrium estimates. Table F3 presents the primary estimates of clients served, based on a two-year phase-in, estimates without a phase-in, and estimates with a three-year phase-in assumption.

TABLE F3—TITLE X CLIENTS WITH DIFFERENT PHASE-IN ASSUMPTIONS

Year	Baseline	Proposed rule, 2-year phase-in	Proposed rule, no phase-in	Proposed rule, 3-year phase-in
2022 .....	2,512,066	3,247,958	3,983,849	3,002,660
2023 .....	2,512,066	3,983,849	3,983,849	3,493,255
2024 .....	2,512,066	3,983,849	3,983,849	3,983,849
2025 .....	2,512,066	3,983,849	3,983,849	3,983,849
2026 .....	2,512,066	3,983,849	3,983,849	3,983,849

Table F4 calculates the effect of the final rule with different phase-in assumptions. These estimates are reported by year, as well as in present value and annualized for the five-year

time horizon of the analysis, applying a three percent and a seven percent discount rate. Compared to the primary estimates, the assumption of no phase-in yields annualized effects of the final

rule that are approximately 12 percent higher. Assuming a three-year phase-in yields annualized effects that are about 12 percent lower than the primary estimates.

TABLE F4—EFFECT OF THE PROPOSED RULE ON TITLE X CLIENTS WITH DIFFERENT PHASE-IN ASSUMPTIONS

Year	Proposed rule, 2-year phase-in	Proposed rule, no phase-in	Proposed rule, 3-year phase-in
2022 .....	735,892	1,471,783	490,594
2023 .....	1,471,783	1,471,783	981,189
2024 .....	1,471,783	1,471,783	1,471,783
2025 .....	1,471,783	1,471,783	1,471,783
2026 .....	1,471,783	1,471,783	1,471,783
PDV, 3% .....	6,025,877	6,740,335	5,325,293
PDV, 7% .....	5,346,852	6,034,601	4,689,098
Annualized, 3% .....	1,315,778	1,471,783	1,162,802
Annualized, 7% .....	1,304,047	1,471,783	1,143,627

#### g. Analysis of Regulatory Alternatives to the Proposed Rule

The Department analyzed two alternatives to the approach under the final rule. The Department considered one option to maintain many elements of the 2019 rule and to impose additional restrictions on grantees. This

approach would exacerbate the trends of reduced Title X grantees, subrecipients, service sites, and clients served that we have observed under the 2019 rule. Second, the Department considered revising the 2019 rule by readopting many elements of the 2000 regulations, but adopting additional flexibilities for

grantees and reducing programmatic oversight. However, experience suggests the compliance regime as it existed prior to the 2019 rule was effective.

#### IV. Environmental Impact

The Department has determined under 21 CFR 25.30(k) that this action

is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### V. Paperwork Reduction Act

This final rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. No public comments were provided on the proposed information collections for § 59.4, 59.5, and 59.7 proposed in the NPRM. OMB filed comment on this NPRM and assigned OMB Control Number 0970–0211. As previously stated in the preamble, the final rule is revoking the 2019 final rule in its entirety. As a result, the final rule does not include information data collection required under § 59.5(a)(12) to provide documentation or assurance to HHS of a plan to comply with state notifications laws, and it does not include the

requirement under § 59.5(a)(13) to report information to HHS on subrecipients. However, additional information collection was identified related to § 59.4, 59.5, and 59.7. The final rule is revising the information collections to reflect the additional estimated burden for the Title X grant requirements under § 59.4, 59.5, and 59.7. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1.

§ 59.4 requires Title X grant applicants to describe how the proposed project would satisfy the regulatory requirements for the Title X program in their applications, including the specific project requirements under § 59.5 and the grant review criteria specified under § 59.7. We estimate that the time necessary for each Title X applicant to include this information in their grant applications would be 70 hours. All other reporting burden associated with grant applications is already approved via existing *Grants.gov* common forms.

*Burden of Response:* The Department is committed to leveraging existing grant, contract, annual reporting, and other Departmental forms where possible, rather than creating additional, separate forms for recipients to sign. The burden for describing the Title X grant requirements is the cost for each applicant to include this information in their grant applications. The labor cost would consist of a medical and health service manager spending an average of 70 hours writing and incorporating the Title X program information in their grant applications. The Department estimates the number of applicants at 136, based on the number of eligible applicants who applied to the Title X national grant competition before the 2019 final rule was in effect. The mean hourly wage (not including benefits and overhead) is \$55.37 per hour for the medical and health service manager.<sup>27</sup> The labor cost per application is \$3,875.90. (\$55.37 × 70 hours), and the total labor cost is \$527,122.40 (\$3,875.90 × 136 applications).

TABLE 1—ESTIMATED BURDEN FOR DESCRIBING THE TITLE X GRANT REQUIREMENTS IN THE GRANT APPLICATION FOLLOWING PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Applicant responses	Hourly rate (\$)	Burden per response (hours)	Total annual burden (hours)	Labor cost of application (\$)
Title X Grant Requirements .....	0970–0211	136	55.37	70	9,520	527,122.40
Total cost .....	.....	.....	.....	.....	.....	527,122.40

#### List of Subjects in 42 CFR Part 59

Family planning, Grant programs-health, Health professions, Abortion, Birth control, Title X.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

#### 42 CFR Part 59

#### PART 59—GRANTS FOR FAMILY PLANNING

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is revised to read as follows:

##### Subpart A—Project Grants for Family Planning Services

Sec.

59.1 To what programs do these regulations apply?

59.2 Definitions.

59.3 Who is eligible to apply for a family planning services grant?

59.4 How does one apply for a family planning services grant?

59.5 What requirements must be met by a family planning project?

59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

59.8 How is a grant awarded?

59.9 For what purposes may grant funds be used?

59.10 Confidentiality.

59.11 Additional conditions.

**Authority:** 42 U.S.C. 300a-4.

##### Subpart A—Project Grants for Family Planning Services

##### § 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health

Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

##### § 59.2 Definitions.

As used in this subpart:

*Act* means the Public Health Service Act, as amended.

*Adolescent-friendly health services* are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

*Clinical services provider* includes physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related

<sup>27</sup> 2019 labor costs for medical and health service managers, <https://www.bls.gov/oes/2019/may/oes119111.htm>.

preventive health, and basic infertility care.

*Client-centered care* is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.

*Culturally and linguistically appropriate services* are respectful of and responsive to the health beliefs, practices and needs of diverse patients.

*Family* means a social unit composed of one person, or two or more persons living together, as a household.

*Family planning services* include a broad range of medically approved services, which includes Food and Drug Administration (FDA)-approved contraceptive products and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

*Health equity* is when all persons have the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

*Inclusive* is when all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

*Low-income family* means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

*Nonprofit*, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

*Quality healthcare* is safe, effective, client-centered, timely, efficient, and equitable.

*Secretary* means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

*Service site* is a clinic or other location where Title X services are provided to clients. Title X recipients and/or their subrecipients may have service sites.

*State* includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, et al.), the Marshall Islands, the Federated State of Micronesia, and the Republic of Palau.

*Trauma-informed* means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.

#### **§ 59.3 Who is eligible to apply for a family planning services grant?**

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

#### **§ 59.4 How does one apply for a family planning services grant?**

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

#### **§ 59.5 What requirements must be met by a family planning project?**

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.<sup>1</sup>

(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

(4) Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning.<sup>2</sup> A project must:

(i) Offer pregnant clients the opportunity to be provided information

<sup>1</sup> 42 U.S.C. 300a-8 provides that any officer or employee of the United States, officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.

<sup>2</sup> Providers may separately be covered by federal statutes protecting conscience and/or civil rights.

and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and, referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to clients from low-income families.

(7) Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(i) Family income should be assessed before determining whether copayments or additional fees are charged.

(ii) With regard to insured clients, clients whose family income is at or below 250 percent of the FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

(9) Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.

(10) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed

under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required.

(11)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for opportunities for community education, participation, and engagement to:

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a clinical services

provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or their designee on the project staff.

(8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

#### **§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?**

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The committee shall consist of no fewer than five members and up to as many members the recipient



determines, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

**§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?**

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of clients, and, in particular, the number of low-income clients to be served;

(2) The extent to which family planning services are needed locally;

(3) The ability of the applicant to advance health equity;

(4) The relative need of the applicant;

(5) The capacity of the applicant to make rapid and effective use of the federal assistance;

(6) The adequacy of the applicant's facilities and staff;

(7) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

(8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of an estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

**§ 59.8 How is a grant awarded?**

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to re compete for funds. This anticipated period will usually be for three to five years.

(b) Generally, the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved

application or portion of an approved application.

**§ 59.9 For what purpose may grant funds be used?**

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75.

**§ 59.10 Confidentiality.**

(a) All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.

(b) To the extent practical, Title X projects shall encourage family participation.<sup>3</sup> However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.

**§ 59.11 Additional conditions.**

The Secretary may, with respect to any grant, impose additional conditions prior to, at the time of, or during any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[FR Doc. 2021-21542 Filed 10-4-21; 4:15 pm]

**BILLING CODE 4150-30-P**

<sup>3</sup> 42 U.S.C. 300(a).



Office of  
Population Affairs

# ***Dobbs v. Jackson Women's Health Organization U.S. Supreme Court Decision: Impact on Title X Program***

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QUESTIONS & ANSWERS FOR TITLE X RECIPIENTS

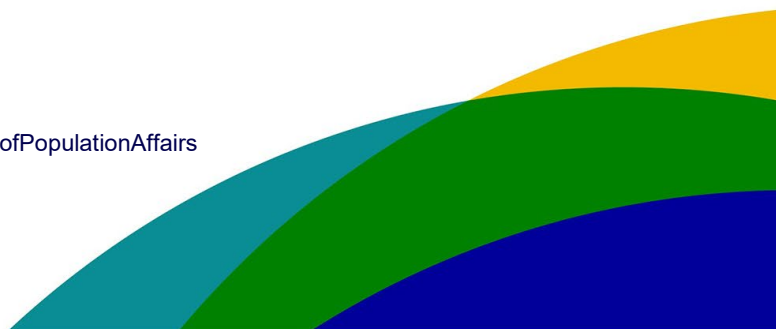
**Updated November 2022**

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## **HHS Office of Population Affairs**

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## Questions & Answers Issued October 2022

### 1. Where should I look for answers about Dobbs and its potential impact on my project?

We recommend you start by contacting your Project Officer and visiting [MAX.gov](https://www.max.gov).

For technical assistance in developing clinical protocols or with other clinical service delivery questions, contact the [National Clinical Training Center on Family Planning \(NCTCFP\)](#).

For other technical assistance, contact the [Reproductive Health National Training Center \(RHNTC\)](#).

For general information not limited to Title X, please review the following:

- **ReproductiveRights.org:** U.S. Department of Health and Human Services website provides accurate and up-to-date information about access to and coverage of reproductive health care and resources.
- **Executive Order Protecting Access to Reproductive Health Care Services:** On July 8, 2022, President Biden signed an Executive Order. Read the Executive Order [here](#) and factsheet [here](#).
- **Executive Order On Securing Access to Reproductive and Other Healthcare Services:** On August 3, 2022, President Biden signed a subsequent Executive Order. Read the Executive Order [here](#) and factsheet [here](#).
- **HIPAA Notice:** Notice regarding [HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care](#).
- **Federal Trade Commission Notice:** This [Federal Trade Commission \(FTC\) notice](#) covers enforcing the law against the illegal sharing of highly sensitive data.

### 2. If a Title X recipient is located in a state with laws that could be interpreted to prohibit abortion counseling and referral, is the recipient required to comply with the state laws or with the Title X regulations, which require recipients to provide abortion referral and counseling?

While OPA is unaware of any current state laws that expressly conflict, Title X recipients must still follow Federal regulatory requirements, such as providing nondirective counseling and referrals for abortion on request. However, some practices may be impacted. For example, where a state has banned certain abortions, referrals in those circumstances will need to be made out of state.

### 3. Can Federal recipients use grant funds for legal services directly related to their grant award?

It is possible that recipients can use their grant funds for legal services related to their project. Decisions about allowability of costs are made by the Office of the Assistant Secretary for Health (OASH) Grants Management Officer (GMO) based upon factors set out in grants administration regulations at 45 CFR § 75.459 ("Professional service costs") and 45 CFR §

75.435 (“Defense and prosecution of criminal and civil proceedings, claims, appeals, and patent infringements”). Recipients should review 45 CFR § 75.459 and 45 CFR § 75.435 and discuss with the GMO for final determination.

45 CFR § 75.459 Professional service costs - <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-E/subject-group-ECFR5d90ba314caea08/section-75.459>

45 CFR § 75.435 Defense and prosecution of criminal and civil proceedings, claims, appeals, and patent infringements - <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-E/subject-group-ECFR5d90ba314caea08/section-75.435>

**4. Does the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* affect the provision of follow-up care for early pregnancy loss; miscarriage; or self-managed abortion at Title X service sites?**

It does not. Title X recipients are required to provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices. (42 CFR § 59.5(b)(1))

For technical assistance in developing clinical protocols or with other clinical service delivery questions, contact the [National Clinical Training Center on Family Planning \(NCTCFP\)](#).

**5. Some of our subrecipients are concerned about reporting pregnancy test results in their electronic medical record (EMR), especially since we have to submit Family Planning Annual Report (FPAR) data. How do we ensure the confidentiality of our clients’ medical records?**

Title X recipients should ensure that their internal controls for all Title X client data ensure confidentiality. Please refer to the question answered in the June Q&A below: “*What is Title X’s requirement on maintaining client confidentiality?*” for more information on client confidentiality.

The [FPAR 2.0 Q&A](#) in the “Data Privacy” section clarifies OPA’s deidentifying process to ensure security of client data.

For technical assistance regarding client data privacy and confidentiality, contact the [Reproductive Health National Training Center \(RHNTC\)](#).

**6. Does Title X or OPA provide legal protections if state laws change to be more restrictive than what Title X requires? (i.e., providers or clients being penalized for naming/referring/or accessing abortions services)?**

It is possible that recipients can use their grant funds for legal services related to their project. Please refer to the question answered in the Q&A above: “*Can Federal recipients use grant funds for legal services directly related to their grant award?*” for more information.



To request technical assistance regarding client data privacy and confidentiality, or identify relevant resources, contact the [RHNTC](#).

**7. Can Title X funds be used to purchase home pregnancy tests for clients? (Updated 11/2/2022)**

Yes, Title X funds can be used to purchase home pregnancy tests for clients. Service sites should have protocols established for how they provide the home pregnancy tests to clients under the Title X project and how they ensure confidential, client-centered follow up as needed to promote continuity of care.

For technical assistance in developing clinical protocols or with other clinical service delivery questions, contact the [NCTCFP](#).

## Questions & Answers Issued June 2022

1. **If a Title X recipient begins to see an influx of clients following the Supreme Court decision in *Dobbs, et al. v. Jackson Women's Health Organization*, is the Title X recipient allowed to reallocate funds to account for the change in client volume?**

Title X recipients can submit a request for a budget revision via Grant Solutions at any time if a need arises to reallocate more than 10% of the total budget across approved budget categories. The request should contain documentation explaining the need for the budget revision along with a revised budget (SF-424A) and revised budget narrative. This should be submitted through the GrantSolutions amendment module to begin the review and approval process. The process may take up to 30 days. If approved the grants management officer will issue a notice of award with the budget revision. Guidance on how to submit a budget revision amendment in GrantSolutions can be found on [MAX.gov](https://www.max.gov). Recipients should discuss any potential reallocation of funds with their respective project officer and grants management specialist.

2. **Will OPA be providing Title X recipients with additional funding to address the potential influx in clients that may result from Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*?**

OPA is working to secure additional funding, but unfortunately does not have additional funding available at this time to provide to Title X recipients who may experience an influx in clients following the *Dobbs* Supreme Court decision. If additional funds were to become available at any point, OPA will share the information with all Title X recipients.

3. **Can Title X recipients expand services to a new community or a new state if the need for services changes?**

The Title X program is not a state-based formula grant program, therefore individual Title X project service areas are not limited to individual states. Title X recipients interested in expanding their service area to include new communities, either within or across states, would need to request approval from OPA and GAM for a change in scope of their projects. Requests must be submitted via a change in scope amendment which may take up to 30 days for review. Approval is communicated via a notice of award issued by the grants management officer. Costs may be disallowed if a recipient begins implementing a change in scope prior to its approval.

A change in scope occurs when the recipient proposes changes to project's objectives, aims, or purposes identified in the approved application, such as changing the service area; applying a new technology; adding or eliminating a service delivery site; or making budget changes that cause a project to change substantially from what was originally approved. The [Title X Family Planning Change in Scope Worksheet](#) helps identify elements for clinic closures, new clinics, or other programmatic changes which may require a request for a change in scope to the current Title X family planning project. Recipients are not required to use the worksheet, but can include the completed worksheet with their amendment submission in Grant Solutions.

**4. Can Title X recipients begin to limit receipt of services to only residents from their state if the influx of clients from other states becomes too burdensome?**

No, Title X recipients cannot limit receipt of services to only residents from their states. Title X recipients are required to provide services without the imposition of any durational residency requirement or a requirement that the client be referred by a physician. (42 CFR § 59.5(b)(5))

**5. Can Title X recipients remove pregnancy testing and counseling from their Title X projects?**

Title X recipients are required to provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (**including pregnancy testing and counseling**, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. (42 CFR § 59.5(a)(1))

**As a result of the requirement in § 59.5(a)(1), Title X recipients cannot completely remove pregnancy testing and counseling services from their Title X projects.** Title X service sites are expected to provide most, if not all, of acceptable and effective medically approved family planning methods and services on site and to detail the referral process for family planning methods and services that are unavailable on-site. However, as long as the entire Title X project offers a broad range of acceptable and effective medically approved family planning methods and services, including pregnancy testing and counseling, not all individual service sites participating in the project must offer the broad range of methods and services.

Furthermore, Title X recipients are required to ensure that Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested. (42 CFR § 59.5(a)(1))

**6. Given the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, can Title X recipients still provide emergency contraception to clients?**

Yes, Title X recipients are required to provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, preconception health services, and adolescent-friendly health services). (42 CFR § 59.5(a)(1))

Title X recipients may still consider emergency contraception as part of the required broad range of methods and services because it is a medically approved method of contraception. "Emergency contraception is a [FDA-approved] method of birth control you can use if you had sex without using [birth control](#) or if your birth control method did not work correctly. Emergency

contraception pills are different from the abortion pill. If you are already pregnant, emergency contraception pills do not stop or harm your pregnancy.” (womenshealth.gov) Click [here](#) for more information on emergency contraception.

**7. Who should Title X recipients contact with questions about the impact of the U.S. Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*?**

For questions related to the impact of *Dobbs* on their Title X projects, Title X recipients should contact their respective OPA project officers; in addition, they should refer to the Title X Program Handbook for further guidance on all Title X recipient expectations. For questions about *Dobbs* outside the scope of their Title X projects, recipients should contact their private counsel.

**8. Given the Supreme Court decision in *Dobbs v. Jackson Women’s Health Organization*, are Title X recipients still allowed to provide counseling to clients about abortion?**

Not only are Title X recipients **allowed**, but per the 2021 Title X rule, Title X recipients are **required** to offer pregnant clients the opportunity to be provided **information and counseling** regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, **and referral upon request**, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. (42 CFR § 59.5(a)(5))

**9. Given the Supreme Court decision in *Dobbs v. Jackson Women’s Health Organization*, are Title X recipients still allowed to provide clients with counseling and a referral for an abortion?**

Not only are Title X recipients **allowed**, but per the 2021 Title X rule, Title X recipients are **required** to offer pregnant clients the opportunity to be provided **information and counseling** regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, **and referral upon request**, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. (42 CFR § 59.5(a)(5))

However, there are limitations on what abortion counseling and referral is permissible under the statute. A Title X project may not provide pregnancy options counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits. And, while a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient. (65 Fed. Reg. 41281 (July 3, 2000))



Where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR § 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications. (65 Fed. Reg. 41281 (July 3, 2000)).

**10. Can Title X grantees accept referrals from clients living in a different state from where the service site is located?**

Yes, Title X recipients can provide services for clients living outside of the community and state that the service site is located in. Title X recipients are required to provide services without the imposition of any durational residency requirement. (42 CFR § 59.5(b)(5))

**11. Can Title X recipients make referrals for a client to a provider in a different state?**

There are no geographic limits for Title X recipients making referrals for their clients.

Title X recipients are required to provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, **who are in close physical proximity to the Title X site, when feasible**, in order to promote access to services and provide a seamless continuum of care. (42 CFR § 59.5(b)(8))

Title X recipients have flexibility to refer clients for services across state lines if necessary.

**12. Can Title X recipients provide pregnancy counseling via telehealth?**

Yes, Title X recipients are required to provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), **in person or via telehealth**, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices. (42 CFR § 59.5(b)(1))

**13. When providing clients with a referral for an abortion, are Title X recipients allowed to take any further steps to help clients secure an appointment?**

While a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient. (65 Fed. Reg. 41281 (July 3, 2000))

Where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and

is required by 42 CFR § 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications. (65 Fed. Reg. 41281 (July 3, 2000)).

**14. Can Title X projects provide abortion services for clients now in need of such services?**

No, Title X recipients are not allowed to provide abortion as a method of family planning as part of the Title X project. (Section 1008, PHS Act; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022); 42 CFR § 59.5(a)(5))

**15. Are Title X projects allowed to provide medication abortion pills for clients now in need of such services?**

No, Title X recipients are not allowed to provide abortion as a method of family planning as part of the Title X project. (Section 1008, PHS Act; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022); 42 CFR § 59.5(a)(5))

**16. What is the Title X program's requirement on abortion as a method of family planning and abortion counseling and referral?**

Title X recipients are not allowed to provide abortion as a method of family planning as part of the Title X project. (Section 1008, PHS Act; Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 444 (2022); 42 CFR § 59.5(a)(5))

Title X recipients are required to offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. (42 CFR § 59.5(a)(5))

Furthermore, Title X recipients are prohibited from providing services that directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities. (65 Fed. Reg. 41281 (July 3, 2000))

**17. What is considered "sufficient separation" between Title X program activities and abortion-related activities?**

Title X recipients are required to ensure that non-Title X abortion activities are separate and distinct from Title X project activities. Where recipients conduct abortion activities that are not part of the Title X project and would not be permissible if they were, the recipient must ensure that the Title X-supported project is separate and distinguishable from those other activities.

What must be looked at is whether the abortion element in a program of family planning services is so large and so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost. The Title X project is the set of activities the recipient agreed to perform in the relevant grant documents as a condition of receiving Title X funds. A grant applicant may include both project and non-project activities in its grant application, and, so long as these are properly distinguished from each other and prohibited activities are not reflected in the amount of the total approved budget, no problem is created.

Separation of Title X from abortion activities does not require separate recipients or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008. Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities:

- a. a common waiting room is permissible, as long as the costs properly pro-rated;
- b. common staff is permissible, so long as salaries are properly allocated, and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project;
- c. a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project; and
- d. maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated. (65 Fed. Reg. 41281, 41282 (July 3, 2000))

**18. Can Title X recipients use Title X funds to fund speakers to present in opposition to the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*?**

No, Title X recipients are prohibited from promoting or encouraging the use of abortion as a method of family planning through advocacy activities such as providing speakers to debate in opposition to anti-abortion speakers, bringing legal action to liberalize statutes relating to abortion, or producing and/or showing films that encourage or promote a favorable attitude toward abortion as a method of family planning. Films that present only neutral, factual information about abortion are permissible. A Title X project may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project). A Title X project may also discuss abortion as an available alternative when a family planning method fails in a discussion of relative risks of various methods of contraception. (65 Fed. Reg. 41281, 41282 (July 3, 2000))

**19. How can Title X projects support clients with positive pregnancy tests and are experiencing early pregnancy symptoms such as bleeding, nausea and vomiting, or pain?**

For clients experiencing early pregnancy symptoms before the client realizes they are pregnant, and/or immediately following a positive pregnancy test, Title X providers should assess the client and provide clinical care to address their immediate needs.

Subsequently, as detailed in 42 CFR § 59.5(a)(5), providers must offer pregnant clients the opportunity to be provided information and counseling regarding the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, providers must provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

Title X recipients are required to provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, preconception health services, and adolescent-friendly health services). (42 CFR § 59.5(a)(1))

Title X recipients are required to provide services in a manner that ensures equitable and quality service delivery consistent with nationally recognized standards of care. (42 CFR § 59.5(a)(3))

In addition, Title X recipients are required to provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices. (42 CFR § 59.5(b)(1))

## **20. What is Title X's requirement on maintaining client confidentiality?**

As detailed in 42 CFR § 59.10(a), the Title X program requires that all information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form that does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipients must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client. (42 CFR § 59.10(a))





January 25, 2023

To all Title X Services Grantee Project Directors:

The Office of Population Affairs (OPA) is conducting a review of all Title X service grants to ensure compliance with the requirements for nondirective options counseling and referral, as stated in the 2021 Title X implementing regulations at 42 CFR § 59.5(a)(5).

In the past, OPA has exercised enforcement discretion in appropriate circumstances. OPA does not intend to bring enforcement actions against Title X recipients that are making, and continue to make, good-faith efforts to comply with the 2021 Final Rule. OPA is committed to working with grantees to assist them in coming into compliance with the requirements of the 2021 Final Rule.

As part of those good-faith efforts to demonstrate compliance with the requirements for nondirective options counseling and referral set out in the 2021 Title X implementing regulations at 42 CFR § 59.5(a)(5), all Title X services grantees must submit:

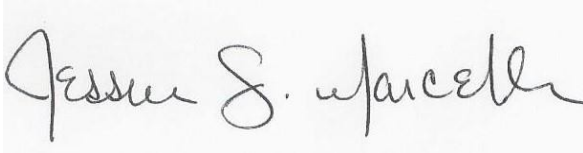
- A copy of the grantee's current policy(ies) and any other supporting documentation (e.g., procedures, subrecipient contract language) for providing nondirective options counseling and referrals within its Title X project. The policy(ies) and supporting documentation must be submitted as a Grant Note in GrantSolutions. If there are any questions or concerns about a grantee's policy(ies) and any other supporting documentation, the OPA project officer will notify the grantee within 2 weeks.
- A written statement, signed by the Project Director and Authorized Official, stating that the grant project is in compliance with the 2021 Title X Final Rule, including the requirements for providing nondirective options counseling and referrals within its Title X project, as required by the 2021 Title X implementing regulations at 42 CFR § 59.5(a)(5). The written statement must be submitted as a Grant Note in GrantSolutions.

**You have until February 6, 2023, to provide the information outlined above to OPA as a Grant Note in GrantSolutions.**

Your failure to provide the requested information and to show that you are in compliance with the 2021 Title X regulatory requirements at 42 CFR § 59.5(a)(5), may result in a determination that you are in material noncompliance with the terms and conditions of your award. If you are found to be out of compliance with the regulatory requirements of your grant, your award can be placed on cash restriction or can be suspended or terminated pursuant to 45 CFR § 75.372(a)(1). You also have the option to voluntarily relinquish your grant if you so choose.

If you have questions, please contact your OPA Project Officer or your GAM Grants Management Specialist.

Very respectfully,



Jessica Swafford Marcella  
Deputy Assistant Secretary for Population Affairs  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Office of Population Affairs



Scott J. Moore -S  
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Scott Moore  
Chief Grants Management Officer  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Grants and Acquisitions Management

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U.S. Public Health Service

February 13, 2023

Tisha Reed, Title X Project Officer  
Department of Health and Human Services  
Telephone: 240.453.6162  
Email: tisha.reed@hhs.gov

Reference: OPA Options counseling referral compliance:

Award #: FPHPA006553-01-00  
Budget Period: 04/01/2022 – 03/31/2023  
Project Period: 04/01/2022 – 03/31/2027

Dear Ms. Reed,

Thank you for your interest in our Title X services. Attached please find our current policy regarding our nondirective counseling to pregnant patients on the range of available options in Tennessee. We believe we are in compliance with regulatory requirements for the scope of allowable practice under Tennessee law. We appreciate these funds which have allowed us to serve almost 44,000 Tennesseans in fiscal year '22.

Sincerely,



Yoshie Darnall, MSN, APN, ANP-BC, WHNP-BC  
Family Planning Program Director  
Division of Family Health and Wellness  
Reproductive and Women's Health



Leslie Meehan, MPA, AICP  
Deputy Commissioner for Population Health (I)

# **PREGNANCY TEST CONDUCTED IN A FAMILY PLANNING VISIT**

## **GENERAL INFORMATION**

Patients requesting/requiring pregnancy tests at the Health Department should be tested on that day and only deferred if unable to accommodate client that day.

## **SUBJECTIVE**

- Complete medical history
- Complete sexual history (5Ps)
  - Practices (vaginal, anal, oral)
  - Partners (number, gender and concurrency)
  - Protection (from STDs/condom use)
  - Past STD history (past personal history and partner history if known)
  - Pregnancy prevention – current and previous methods used, client's preference
- Assess for victimization (examples - sexual or physical abuse, human trafficking, intimate partner/ domestic violence)
- Assess social support system
- Reproductive life plan
- Feelings about possible pregnancy
- Date of LMP
  - If postpartum, use delivery date to calculate EDD and EGA for positive tests
- Dates of unprotected sexual intercourse since LMP

## **OBJECTIVE**

- Urine pregnancy test

## **ASSESSMENT**

- Positive pregnancy test
- Negative pregnancy test

## **PLAN**

- Discuss test results clearly and objectively.
- Patients with positive pregnancy test must be offered the opportunity to be provided information and counseling regarding all options that are legal in the State of Tennessee. Provide unbiased, patient centered, trauma-informed counseling for the option(s) selected by the patient.
- STD Testing
  - Positive pregnancy test result:
    - Collect urine GenProbe for chlamydia and gonorrhea
    - Blood sample for RPR, HIV, HCV
  - Negative pregnancy test result
    - Screen for symptoms, offer testing



## **Pregnancy test positive**

- Calculate estimated gestational age and estimated due date
- Review normal signs/symptoms of pregnancy
- Review warning/danger signs in pregnancy
  - Severe pain
  - Bleeding
  - Dizziness, lightheadedness or syncope
  - Fever
- Provide information about maintaining the health of the mother and unborn child during pregnancy:
  - Importance of early prenatal care – Immediate prenatal care is imperative for patients with a history of pre-term labor
  - Importance of nutrition
  - Provide prenatal vitamins with folic acid
  - Offer appropriate vaccinations
- Stress importance of good dental care during pregnancy and refer if applicable
- Enroll or refer eligible clients to WIC, CHANT, and Presumptive TennCare
  - if patient is not Presumptive TennCare eligible, refer patient to other prenatal care resources and programs
- Advise patient to avoid:
  - Smoking including e-cigarettes and other inhaled nicotine delivery devices.
    - Refer to Baby and Me Tobacco Free Program (BMTFP) if applicable
    - TN Tobacco Quit Line 1-800-QUIT NOW if applicable
  - Alcohol
    - Refer to TN Redline (1-800-889-9789) if applicable
  - Illicit and controlled substance use
    - Refer to TN Redline (1-800-889-9789) if applicable
  - Fish containing high mercury (shark, swordfish, king mackerel, or tilefish)

## **Pregnancy test NEGATIVE**

### **Actively seeking pregnancy**

- Refer to PHN Protocols as needed or desired by patient
  - Preconception Health Services (PHN Protocol 2.105)
  - Fertility Awareness Based Methods (PHN Protocol 2.090)
  - Basic Infertility Counseling (PHN Protocol 2.011)
- Encourage evaluation by PCP or provider

### **Not actively seeking pregnancy or not actively preventing pregnancy**

- Provide contraceptive counseling if requested
  - Offer Same Day Start as requested (PHN Protocol 2.010)
  - Offer Same Day Insertion and referral for LARC (if requested and available)
  - Offer ECP or ECP prescription as requested (PHN Protocol 2.080)
- Discuss preconception health, including folic acid (PHN Protocol 2.105, 3.180)

## REFERENCES

Gavin L, Moskosky, S., Carter, M. et al. Providing Quality Family Planning Services-Recommendations of CDC and the U.S. Office of Population Affairs, 2014. MMWR Morbidity and Mortality Weekly Report 2014;63 (No. RR-04).

Gavin L, Pazol K. Update: Providing Quality Family Planning Services-Recommendations from CDC and the U.S. Office of Population Affairs, 2015. MMWR Morbidity and Mortality Weekly Report 2016;65:231–234.

Gavin L, Pazol K. Update: Providing Quality Family Planning Services-Recommendations from CDC and the U.S. Office of Population Affairs, 2017. MMWR Morbidity and Mortality Weekly Report 2017;66:1383-1385.

<https://www.cdc.gov/zika/hc-providers/reproductive-age/reproductive-planning.html>

<https://www.cdc.gov/zika/hc-providers/reproductive-age/exposure-testing-risks.html>

This protocol has been approved by Jill C. Obrensky, MD, MMHC, FAAP, CHS  
Medical Director on July 1, 2022.



Office of the Assistant Secretary for Health  
Office of Population Affairs  
Washington, D.C. 20201

March 1, 2023

Yoshie Darnall, Program Director  
Ralph Alvarado, Authorized Official  
Grant #FPHPA006553  
710 James Robertson Pkwy  
Nashville, TN 37243

Dear Ms. Darnall & Dr. Alvarado,

On January 25, 2023, the Office of Population Affairs (OPA) began a review of all Title X service grants to ensure compliance with the requirements for nondirective options counseling and referral, in accordance with the 2021 Title X implementing regulations at 42 CFR § 59.5 (a)(5). As stated in the initial request, OPA does not intend to bring enforcement actions against Title X recipients that are making, and continue to make, good-faith efforts to comply with the 2021 Final Rule. OPA is committed to working with grantees to assist them in coming into compliance with the requirements of the 2021 Final Rule.

As part of the request, grantees were required to submit a copy of the current policy(ies) and any other supporting documentation (e.g., procedures, subrecipient contract language) for providing nondirective options counseling and referrals within its Title X project. Additionally, grantees were asked to provide a written statement of compliance with the 2021 Title X Final Rule, including the requirements for providing nondirective options counseling and referrals within its Title X project, signed by the Project Director and Authorized Official. The request was to be fulfilled as a Grant Note within GrantSolutions.

The initial deadline for submission was February 6, 2023. On February 3, 2023, the Tennessee Department of Health requested an extension to February 13, 2023, to give the new commissioner (Dr. Ralph Alvarado, sworn in January 17, 2023) time to review the program and provide a response. We granted the extension that same day. On February 7, 2023, Tennessee requested an additional extension to February 28, 2023, indicating that they had underestimated “the amount of time needed to get the new Commissioner, Dr. Alvarado, knowledgeable about Title X and the requirements.” On February 9, 2023, OPA denied the request for a second extension. We received your submission on February 13, 2023, which included an attached policy entitled “Pregnancy Test Conducted in a Family Planning Visit.”

OPA has reviewed your submission and determined that Tennessee’s policy for providing nondirective options counseling within your Title X project is not in compliance with the Title X regulatory requirements and, therefore, cannot be approved. Specifically, the policy submitted as proof of compliance states that, “Patients with positive pregnancy test must be offered the opportunity to be provided information and counseling regarding all options that are legal in the State of Tennessee”. The inclusion of “legal in the state of Tennessee” is not an acceptable addition to your policy as Title X recipients must still follow all Federal regulatory requirements regarding nondirective options counseling and referrals. In addition, the nursing protocol only included the steps for treating clients who opt to continue a pregnancy. And, while the policy does appear to provide instructions related to providing counseling and referral for prenatal care, no instructions are given for infant care, foster care, adoption, or pregnancy termination, which are all required to be provided upon request.

In order to be in compliance with the 2021 Title X implementing regulations at 42 CFR § 59.5(a)(5), Tennessee's policy must clearly state that the project will offer pregnant clients information and nondirective counseling on each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination (unless clients indicate they do not want such information or counseling). Additionally, projects are required to provide referrals upon client request, including referrals for abortion.

Because OPA is committed to working with grantees to ensure compliance with the 2021 Final Rule, Tennessee has 10 calendar days to provide written assurance to OPA as a Grant Note in GrantSolutions, stating compliance with the Title X nondirective options counseling requirement at 42 CFR § 59.5(a)(5)(ii), signed by your Program Director and Authorizing Official. Failure to provide the requested assurance and supporting documentation, and to show that you are in compliance with the 2021 Title X regulatory requirements at 42 CFR § 59.5(a)(5)(ii), will constitute material noncompliance with the terms and conditions of your award. You must also provide OPA with a revised counseling policy, and a procedure related to referrals as requested in OPA's January 25, 2023, letter.

As another option, you may submit an alternate compliance proposal **by March 13, 2023**. Examples of compliance with 42 CFR § 59.5(a)(5)(ii) include:

- Providing nondirective options counseling on-site by Title X providers on (A) prenatal care and delivery; (B) infant care, foster care, or adoption; and (C) pregnancy termination, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling;
- Providing nondirective options counseling, using a telehealth partnership with another entity, on (A) prenatal care and delivery; (B) infant care, foster care, or adoption; and (C) pregnancy termination, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling ; or
- Providing clients with a referral to another entity (e.g., All-Options Talkline) that provides nondirective options counseling on (A) prenatal care and delivery; (B) infant care, foster care, or adoption; and (C) pregnancy termination, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

Please be aware that if you do not provide a response demonstrating compliance by March 13, 2023, you will be considered out of compliance with the regulatory requirements of the Title X program and, therefore, the terms and conditions of your grant. In that case, your current award can be suspended or terminated pursuant to 45 CFR § 75.372(a)(1) for material noncompliance with the terms and conditions of the award. A termination under this section must be reported to the Office of Management and Budget-designated integrity and performance system, currently the Federal Awardee Performance and Integrity Information System. See 45 CFR § 75.372(b). Inclusion in FAPIIS may affect your ability to obtain future Federal funding.

Alternatively, you may voluntarily relinquish the grant if you so choose. Please contact your GAM Grants Management Specialist, Robin Fuller, for more information on relinquishment. A decision to relinquish your award is not reported to FAPIIS.

OPA will assist you with these concerns with the intent of ensuring compliance with the 2021 Title X implementing regulations. If you have questions, please contact your OPA Project Officer, Tisha Reed.

Very respectfully,





Jessica Swafford Marcella  
Deputy Assistant Secretary for Population Affairs  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Office of Population Affairs

Scott Moore  
Grants Management Officer  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Grants and Acquisitions Management

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U.S. Public Health Service

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Office of the Secretary

Office of the Assistant Secretary for Health  
Office of Population Affairs  
Washington, D.C. 20201

March 20, 2023

Yoshie Darnall, Program Director  
Ralph Alvarado, Authorized Official  
Grant #FPHPA006553  
710 James Robertson Pkwy  
Nashville, TN 37243

Re: Decision not to fund continuation award for FPHPA006553

Dear Ms. Darnall &amp; Dr. Alvarado,

We have received your March 13, 2023, response to our March 1, 2023, letter. Based upon the information you provided in that response, the Office of Population Affairs (OPA) has recommended not providing Fiscal Year (FY) 2023 continuation funding for the Tennessee Department of Health non-competing continuation application for FPHPA006553. According to regulations implementing the Title X family planning services program at 42 CFR part 59, subpart A, "Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government" (42 C.F.R. § 59.8(b)).<sup>1</sup> OPA's recommendation is based on the determination that continued funding is not in the best interest of the government because Tennessee is out of compliance with the Title X regulatory requirements. OPA consulted with the Office of the Assistant Secretary for Health (OASH) Grants and Acquisitions Management Division in formulating its recommendation. Because of OPA's determination of your non-compliance with the Title X regulation, the grants management officer (GMO) has determined that Tennessee is unable to comply with the terms and conditions of the award. The GMO concurs with OPA's recommendation not to fund a continuation award.

**Summary**

On January 25, 2023, the Office of Population Affairs (OPA) began a review of all Title X service grants to ensure compliance with the requirements for nondirective options counseling and referral, in accordance with the 2021 Title X implementing regulations at 42 CFR § 59.5 (a)(5). As stated in the initial request, OPA does not intend to bring enforcement actions against Title X recipients that are making, and continue to make, good-faith efforts to comply with the 2021 Final Rule. OPA is committed to working with grantees to assist them in coming into compliance with the requirements of the 2021 Final Rule.

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<sup>1</sup>Title X regulations also make clear that, "Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional supplemental, continuation, or other award with respect to any approved application or portion of an approved application" (42 CFR 59.8(c)).

As part of the request, grantees were required to submit a copy of the current policy(ies) and any other supporting documentation (e.g., procedures, subrecipient contract language) for providing nondirective options counseling and referrals within its Title X project. Additionally, grantees were asked to provide a written statement of compliance with the 2021 Title X Final Rule, including the requirements for providing nondirective options counseling and referrals within its Title X project, signed by the Project Director and Authorized Official. The request was to be fulfilled as a Grant Note within GrantSolutions.

The initial deadline for submission was February 6, 2023. On February 3, 2023, the Tennessee Department of Health requested an extension to February 13, 2023, to give the new commissioner (Dr. Ralph Alvarado, sworn in January 17, 2023) time to review the program and provide a response. We granted the extension that same day. On February 7, 2023, Tennessee requested an additional extension to February 28, 2023, indicating that they had underestimated "the amount of time needed to get the new Commissioner, Dr. Alvarado, knowledgeable about Title X and the requirements." On February 9, 2023, OPA denied the request for a second extension. We received your submission on February 13, 2023, which included an attached policy entitled "Pregnancy Test Conducted in a Family Planning Visit."

On March 1, 2023, OPA informed you that Tennessee's policy for providing nondirective options counseling within your Title X project is not in compliance with the Title X regulatory requirements and, therefore, cannot be approved. Specifically, the policy submitted as proof of compliance states that, "Patients with positive pregnancy test must be offered the opportunity to be provided information and counseling regarding all options that are legal in the State of Tennessee." The inclusion of "legal in the state of Tennessee" is not an acceptable addition to your policy as Title X recipients must still follow all Federal regulatory requirements regarding nondirective options counseling and referrals. In addition, the nursing protocol only included the steps for treating clients who opt to continue a pregnancy. And, while the policy does appear to provide instructions related to providing counseling and referral for prenatal care, no instructions are given for infant care, foster care, adoption, or pregnancy termination, which are all required to be provided upon request.

In the March 1, letter, OPA also informed Tennessee that in order to be in compliance with the 2021 Title X implementing regulations at 42 CFR § 59.5(a)(5), Tennessee's policy must clearly state that the project will offer pregnant clients information and nondirective counseling on each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination (unless clients indicate they do not want such information or counseling). Additionally, projects are required to provide referrals upon client request, including referrals for abortion. OPA instructed Tennessee to provide written assurance, stating that the project is in compliance with the Title X nondirective options counseling requirement at 42 CFR § 59.5(a)(5)(ii) and supporting documentation showing compliance, by March 13, 2023. OPA also requested that Tennessee provide OPA with a revised counseling policy, and a procedure related to referrals. Finally, in the March 1, 2023, letter, Tennessee was also given the option to submit an alternate compliance proposal, which included three examples of compliance with 42 CFR § 59.5(a)(5)(ii).

On March 13, 2023, you responded that Tennessee's nondirective policy appears to be in compliance with Title X given the standard of care in Tennessee. You indicated that, pursuant to Tennessee law, Title X subgrantees' physicians can comply with the Title X nondirective options counseling and referral requirements set out in 42 CFR § 59.5(a)(5) by referring patients for "terminat[ing] the pregnancy of a woman known to be pregnant" when the termination is with intent "to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus." Tenn. Code Ann. § 39-15-213(a)(1) (excluding such procedures from the definition of abortion). For these reasons, Tennessee does not construe the phrase "pregnancy termination" to include every possible method of "pregnancy termination," such as abortion.

OPA has reviewed your statement and determined that Tennessee's policy for providing nondirective options counseling and referral within your Title X project remains not in compliance with the Title X regulatory requirements and, therefore, the terms and conditions of your grant. As we indicated in our March 1, 2023, letter, Title X recipients must follow all Federal regulatory requirements regarding nondirective options counseling and referrals, including providing referrals for abortion upon client request.<sup>2</sup> We understand that in some circumstances, those referrals will need to be made out of state. As noted above, based upon this determination of noncompliance with the Title X regulatory requirements, OPA has recommended not providing Fiscal Year (FY) 2023 continuation funding for the Tennessee Department of Health non-competing continuation application for FPHPA006553, as continued funding is not in the best interest of the government.

### Next Steps

We will issue a notice of award with a project period end date of March 31, 2023 and include instructions for closing out your award. Requests for a no-cost extension will be considered if submitted promptly in order to complete activities for an orderly shutdown of award activities (e.g., completing already scheduled appointments for services). Your complete close out documentation must be submitted within 120 days of the end of the project period.

Please contact your GAM Grants Management Specialist, Robin Fuller, for more information on closing out your award. OPA will assist you with closing out the programmatic reporting requirements of your award. If you have questions, please contact your OPA Project Officer, Tisha Reed.

Very respectfully,

Jessica S. Marcella  
-S  
Digitally signed by Jessica S. Marcella  
Date: 2023.03.20 10:27:42 -0400

Jessica Swafford Marcella  
Deputy Assistant Secretary for Population Affairs  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Office of Population Affairs

Scott Moore  
Grants Management Officer  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Grants and Acquisitions Management

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U.S. Public Health Service

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<sup>2</sup>The abortion counseling and referral requirements were made clear in the 2021 Title X Final Rule. 86 Fed. Reg. 56144 (2021).





Displaying the eCFR in effect on 3/20/2023. ⓘ

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**Appendix A to Part 16**

What Disputes the Board Reviews

## ⊙ PART 16 - PROCEDURES OF THE DEPARTMENTAL GRANT APPEALS BOARD

**Authority:** 5 U.S.C. 301 and secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix.

**Source:** 46 FR 43817, Aug. 31, 1981, unless otherwise noted.

### ⊙ § 16.1 What this part does.

This part contains requirements and procedures applicable to certain disputes arising under the HHS programs described in appendix A. This part is designed to provide a fair, impartial, quick and flexible process for appeal from written final decisions. This part supplements the provisions in part 75 of this title.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

## § 16.2 Definitions.

- (a) **Board** means the Departmental Grant Appeals Board of the Department of Health and Human Services. Reference below to an action of *the Board* means an action of the Chair, another Board member, or Board staff acting at the direction of a Board member. In certain instances, the provisions restrict action to particular Board personnel, such as the Chair or a Board member assigned to a case.
- (b) Other terms shall have the meaning set forth in part 75 of this title, unless the context below otherwise requires.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

## § 16.3 When these procedures become available.

Before the Board will take an appeal, three circumstances must be present:

- (a) The dispute must arise under a program which uses the Board for dispute resolution, and must meet any special conditions established for that program. An explanation is contained in appendix A.
- (b) The appellant must have received a final written decision, and must appeal that decision within 30 days after receiving it. Details of how final decisions are developed and issued, and what must be in them, are contained in 45 CFR 75.374.
- (c) The appellant must have exhausted any preliminary appeal process required by regulation. For example, see 42 CFR part 50 (subpart D) for Public Health Service programs. In such cases, the *final written decision* required for the Board's review is the decision resulting from the preliminary review or appeal process. appendix A contains further details.

[46 FR 43817, Aug. 31, 1981, as amended at 62 FR 38218, July 17, 1997; 81 FR 3012, Jan. 20, 2016]

## § 16.4 Summary of procedures below.

The Board's basic process is review of a written record (which both parties are given ample opportunity to develop), consisting of relevant documents and statements submitted by both parties (see § 16.8). In addition, the Board may hold an informal conference (see § 16.10). The informal conference primarily involves questioning of the participants by a presiding Board member. Conferences may be conducted by telephone conference call. The written record review also may be supplemented by a hearing involving an opportunity for examining evidence and witnesses, cross-examination, and oral argument (see § 16.11). A hearing is more expensive and time-consuming than a determination on the written record alone or with an informal conference. Generally, therefore, the Board will schedule a hearing only if the Board determines that there are complex issues or material facts in dispute, or that the Board's review would otherwise be significantly enhanced by a hearing. Where the amount in dispute is \$25,000 or less, there are special expedited procedures (see § 16.12 of this part). In all cases, the Board has the flexibility to modify procedures to ensure fairness, to avoid delay, and to accommodate the peculiar needs of a given case. The Board makes maximum feasible use of preliminary informal steps to refine issues and to encourage resolution by the parties. The Board also has the capability to provide mediation services (see § 16.18).

## § 16.5 How the Board operates.

- (a) The Board's professional staff consists of a Chair (who is also a Board member) and full- and part-time Board members, all appointed by the Secretary; and a staff of employees and consultants who are attorneys or persons from other relevant disciplines, such as accounting.
- (b) The Chair will assign a Board member to have lead responsibility for each case (the "presiding Board member"). The presiding Board member will conduct the conference or hearing, if one is held. Each decision of the Board is issued by the presiding Board member and two other Board members.
- (c) The Board staff assists the presiding Board member, and may request information from the parties; conduct telephone conference calls to request information, to clarify issues, or to schedule events; and assist in developing decisions and other documents in a case.
- (d) The Chair will assure that no Board or staff member will participate in a case where his or her impartiality could reasonably be questioned.
- (e) The Board's powers and responsibilities are set forth in § 16.13.

### § 16.6 Who represents the parties.

The appellant's notice of appeal, or the first subsequent submission to the Board, should specify the name, address and telephone number of the appellant's representative. In its first submission to the Board and the appellant, the respondent (i.e., the federal party to the appeal) should specify the name, address and telephone number of the respondent's representative.

### § 16.7 The first steps in the appeal process: The notice of appeal and the Board's response.

- (a) As explained in 45 CFR 75.374, a prospective appellant must submit a notice of appeal to the Board within 30 days after receiving the final decision. The notice of appeal must include a copy of the final decision, a statement of the amount in dispute in the appeal, and a brief statement of why the decision is wrong.
- (b) Within ten days after receiving the notice of appeal, the Board will send an acknowledgment, enclose a copy of these procedures, and advise the appellant of the next steps. The Board will also send a copy of the notice of appeal, its attachments, and the Board's acknowledgment to the respondent. If the Board Chair has determined that the appeal does not meet the conditions of § 16.3 or if further information is needed to make this determination, the Board will notify the parties at this point.

*[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]*

### § 16.8 The next step in the appeal process: Preparation of an appeal file and written argument.

Except in expedited cases (generally those of \$25,000 or less; see § 16.12 for details), the appellant and the respondent each participate in developing an appeal file for the Board to review. Each also submits written argument in support of its position. The responsibilities of each are as follows:

- (a) **The appellant's responsibility.** Within 30 days after receiving the acknowledgment of the appeal, the appellant shall submit the following to the Board (with a copy to the respondent):
  - (1) An appeal file containing the documents supporting the claim, tabbed and organized chronologically and accompanied by an indexed list identifying each document. The appellant should include only those documents which are important to the Board's decision on the issues in the case.
  - (2) A written statement of the appellant's argument concerning why the respondent's final decision is wrong (appellant's brief).
- (b) **The respondent's responsibility.** Within 30 days after receiving the appellant's submission under paragraph (a) of this section, the respondent shall submit the following to the Board (with a copy to the appellant):

- (1) A supplement to the appeal file containing any additional documents supporting the respondent's position, organized and indexed as indicated under paragraph (a) of this section. The respondent should avoid submitting duplicates of documents submitted by the appellant.
- (2) A written statement (respondent's brief) responding to the appellant's brief.
- (c) **The appellant's reply.** Within 15 days after receiving the respondent's submission, the appellant may submit a short reply. The appellant should avoid repeating arguments already made.
- (d) **Cooperative efforts.** Whenever possible, the parties should try to develop a joint appeal file, agree to preparation of the file by one of them, agree to facts to eliminate the need for some documents, or agree that one party will submit documents identified by the other.
- (e) **Voluminous documentation.** Where submission of all relevant documents would lead to a voluminous appeal file (for example where review of a disputed audit finding of inadequate documentation might involve thousands of receipts), the Board will consult with the parties about how to reduce the size of the file.

#### • § 16.9 How the Board will promote development of the record.

The Board may, at the time it acknowledges an appeal or at any appropriate later point, request additional documents or information; request briefing on issues in the case; issue orders to show cause why a proposed finding or decision of the Board should not become final; hold preliminary conferences (generally by telephone) to establish schedules and refine issues; and take such other steps as the Board determines appropriate to develop a prompt, sound decision.

#### • § 16.10 Using a conference.

- (a) Once the Board has reviewed the appeal file, the Board may, on its own or in response to a party's request, schedule an informal conference. The conference will be conducted by the presiding Board member. The purposes of the conference are to give the parties an opportunity to make an oral presentation and the Board an opportunity to clarify issues and question both parties about matters which the Board may not yet fully understand from the record.
- (b) If the Board has decided to hold a conference, the Board will consult or correspond with the parties to schedule the conference, identify issues, and discuss procedures. The Board will identify the persons who will be allowed to participate, along with the parties' representatives, in the conference. The parties can submit with their briefs under § 16.8 a list of persons who might participate with them, indicating how each person is involved in the matter. If the parties wish, they may also suggest questions or areas of inquiry which the Board may wish to pursue with each participant.
- (c) Unless the parties and the Board otherwise agree, the following procedures apply:
  - (1) Conferences will be recorded at Department expense. On request, a party will be sent one copy of the transcript. The presiding Board member will insure an orderly transcript by controlling the sequence and identification of speakers.
  - (2) Only in exceptional circumstances will documents be received at a conference. Inquiry will focus on material in the appeal file. If a party finds that further documents should be in the record for the conference, the party should supplement the appeal file, submitting a supplementary index and copies of the documents to the Board and the other party not less than ten days prior to the conference.
  - (3) Each party's representative may make an oral presentation. Generally, the only oral communications of other participants will consist of statements requested by the Board or responses to the Board's questions. The Board will allow reply comment, and may allow short closing statements. On request, the Board may allow the participants to question each other.
  - (4) There will be no post-conference submissions, unless the Board determines they would be helpful to resolve the case. The Board may require or allow the parties to submit proposed findings and conclusions.



⦿ § 16.11 Hearing.

- (a) **Electing a hearing.** If the appellant believes a hearing is appropriate, the appellant should specifically request one at the earliest possible time (in the notice of appeal or with the appeal file). The Board will approve a request (and may schedule a hearing on its own or in response to a later request) if it finds there are complex issues or material facts in dispute the resolution of which would be significantly aided by a hearing, or if the Board determines that its decisionmaking otherwise would be enhanced by oral presentations and arguments in an adversary, evidentiary hearing. The Board will also provide a hearing if otherwise required by law or regulation.
- (b) **Preliminary conference before the hearing.** The Board generally will hold a prehearing conference (which may be conducted by telephone conference call) to consider any of the following: the possibility of settlement; simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; scheduling the hearing; and any other matter that may aid in resolving the appeal. Normally, this conference will be conducted informally and off the record; however, the Board, after consulting with the parties, may reduce results of the conference to writing in a document which will be made part of the record, or may transcribe proceedings and make the transcript part of the record.
- (c) **Where hearings are held.** Hearings generally are held in Washington, DC. In exceptional circumstances, the Board may hold the hearing at an HHS Regional Office or other convenient facility near the appellant.
- (d) **Conduct of the hearing.**
  - (1) The presiding Board member will conduct the hearing. Hearings will be as informal as reasonably possible, keeping in mind the need to establish an orderly record. The presiding Board member generally will admit evidence unless it is determined to be clearly irrelevant, immaterial or unduly repetitious, so the parties should avoid frequent objections to questions and documents. Both sides may make opening and closing statements, may present witnesses as agreed upon in the prehearing conference, and may cross-examine. Since the parties have ample opportunity to develop a complete appeal file, a party may introduce an exhibit at the hearing only after explaining to the satisfaction of the presiding Board member why the exhibit was not submitted earlier (for example, because the information was not available).
  - (2) The Board may request the parties to submit written statements of witnesses to the Board and each other prior to the hearing so that the hearing will primarily be concerned with cross-examination and rebuttal.
  - (3) False statements of a witness may be the basis for criminal prosecution under sections 287 and 1001 of Title 18 of the United States Code.
  - (4) The hearing will be recorded at Department expense.
- (e) **Procedures after the hearing.** The Board will send one copy of the transcript to each party as soon as it is received by the Board. At the discretion of the Board, the parties may be required or allowed to submit post-hearing briefs or proposed findings and conclusions (the parties will be informed at the hearing). A party should note any major prejudicial transcript errors in an addendum to its post-hearing brief (or if no brief will be submitted, in a letter submitted within a time limit set by the Board).

⦿ § 16.12 The expedited process.

- (a) **Applicability.** Where the amount in dispute is \$25,000 or less, the Board will use these expedited procedures, unless the Board Chair determines otherwise under paragraph (b) of this section. If the Board and the parties agree, the Board may use these procedures in cases of more than \$25,000.
- (b) **Exceptions.** If there are unique or unusually complex issues involved, or other exceptional circumstances, the Board may use additional procedures.
- (c) **Regular expedited procedures.**

- (1) Within 30 days after receiving the Board's acknowledgment of the appeal (see § 16.7), each party shall submit to the Board and the other party any relevant background documents (organized as required under § 16.8), with a cover letter (generally not to exceed ten pages) containing any arguments the party wishes to make.
- (2) Promptly after receiving the parties' submissions, the presiding Board member will arrange a telephone conference call to receive the parties' oral comments in response to each other's submissions. After notice to the parties, the Board will record the call. The Board member will advise the parties whether any opportunities for further briefing, submissions or oral presentations will be established. Cooperative efforts will be encouraged (see § 16.8(d)).
- (3) The Board may require the parties to submit proposed findings and conclusions.
- (d) ***Special expedited procedures where there has already been review.*** Some HHS components (for example, the Public Health Service) use a board or other relatively independent reviewing authority to conduct a formal preliminary review process which results in a written decision based on a record including documents or statements presented after reasonable notice and opportunity to present such material. In such cases, the following rules apply to appeals of \$25,000 or less instead of those under paragraph (c) of this section:
  - (1) Generally, the Board's review will be restricted to whether the decision of the preliminary review authority was clearly erroneous. But if the Board determines that the record is inadequate, or that the procedures under which the record was developed in a given instance were unfair, the Board will not be restricted this way.
  - (2) Within 30 days after receiving the Board's acknowledgment of appeal (see § 16.7), the parties shall submit the following:
    - (i) The appellant shall submit to the Board and the respondent a statement why the decision was clearly erroneous. Unless allowed by the Board after consultation with the respondent, the appellant shall not submit further documents.
    - (ii) The respondent shall submit to the Board the record in the case. If the respondent has reason to believe that all materials in the record already are in the possession of the appellant, the respondent need only send the appellant a list of the materials submitted to the Board.
    - (iii) The respondent may, if it wishes, submit a statement why the decision was not clearly erroneous.
  - (3) The Board, in its discretion, may allow or require the parties to present further arguments or information.

### § 16.13 Powers and responsibilities.

In addition to powers specified elsewhere in these procedures, Board members have the power to issue orders (including "show cause" orders); to examine witnesses; to take all steps necessary for the conduct of an orderly hearing; to rule on requests and motions, including motions to dismiss; to grant extensions of time for good reasons; to dismiss for failure to meet deadlines and other requirements; to close or suspend cases which are not ready for review; to order or assist the parties to submit relevant information; to remand a case for further action by the respondent; to waive or modify these procedures in a specific case with notice to the parties; to reconsider a Board decision where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

### § 16.14 How Board review is limited.

The Board shall be bound by all applicable laws and regulations.

### § 16.15 Failure to meet deadlines and other requirements.

- (a) Since one of the objectives of administrative dispute resolution is to provide a decision as fast as possible consistent with fairness, the Board will not allow parties to delay the process unduly. The Board may grant extensions of time, but only if the party gives a good reason for the delay.
- (b) If the appellant fails to meet any filing or procedural deadlines, appeal file or brief submission requirements, or other requirements established by the Board, the Board may dismiss the appeal, may issue an order requiring the party to show cause why the appeal should not be dismissed, or may take other action the Board considers appropriate.
- (c) If the respondent fails to meet any such requirements, the Board may issue a decision based on the record submitted to that point or take such other measures as the Board considers appropriate.

⊙ **§ 16.16 Parties to the appeal.**

- (a) The only parties to the appeal are the appellant and the respondent. If the Board determines that a third person is a real party in interest (for example, where the major impact of an audit disallowance would be on the grantee's contractor, not on the grantee), the Board may allow the third person to present the case on appeal for the appellant or to appear with a party in the case, after consultation with the parties and if the appellant does not object.
- (b) The Board may also allow other participation, in the manner and by the deadlines established by the Board, where the Board decides that the intervenor has a clearly identifiable and substantial interest in the outcome of the dispute, that participation would sharpen issues or otherwise be helpful in resolution of the dispute, and that participation would not result in substantial delay.

⊙ **§ 16.17 Ex parte communications (communications outside the record).**

- (a) A party shall not communicate with a Board or staff member about matters involved in an appeal without notice to the other party. If such communication occurs, the Board will disclose it to the other party and make it part of the record after the other party has an opportunity to comment. Board members and staff shall not consider any information outside the record (see § 16.21 for what the record consists of) about matters involved in an appeal.
- (b) The above does not apply to the following: Communications among Board members and staff; communications concerning the Board's administrative functions or procedures; requests from the Board to a party for a document (although the material submitted in response also must be given to the other party); and material which the Board includes in the record after notice and an opportunity to comment.

⊙ **§ 16.18 Mediation.**

- (a) *In cases pending before the Board.* If the Board decides that mediation would be useful to resolve a dispute, the Board, in consultation with the parties, may suggest use of mediation techniques and will provide or assist in selecting a mediator. The mediator may take any steps agreed upon by the parties to resolve the dispute or clarify issues. The results of mediation are not binding on the parties unless the parties so agree in writing. The Board will internally insulate the mediator from any Board or staff members assigned to handle the appeal.
- (b) *In other cases.* In any other grants dispute, the Board may, within the limitations of its resources, offer persons trained in mediation skills to aid in resolving the dispute. Mediation services will only be offered at the request, or with the concurrence, of a responsible federal program official in the program under which the dispute arises. The Board will insulate the mediator if any appeal subsequently arises from the dispute.

⊙ **§ 16.19 How to calculate deadlines.**

In counting days, include Saturdays, Sundays, and holidays; but if a due date would fall on a Saturday, Sunday or Federal holiday, then the due date is the next Federal working day.

• **§ 16.20 How to submit material to the Board.**

- (a) Submissions should be addressed to the Board's current mailing address: Department of Health and Human Services, Departmental Appeals Board, Appellate Division—MS 6127, 330 Independence Ave. SW., Cohen Building—Rm. G-644, Washington, DC 20201; however, submissions to the Board in certain types of cases may be made by electronic filing using DAB E-File at <https://dab.efile.hhs.gov>. Changes to the mailing address will be made available on the Board's Web site at [www.hhs.gov/dab/divisions/appellate](http://www.hhs.gov/dab/divisions/appellate).
- (b) All submissions after the notice of appeal should identify the Board's docket number (the Board's acknowledgement under § 16.7 will specify the docket number).
- (c) Unless the Board otherwise specifies, parties shall submit to the Board an original and two copies of all materials. Each submission other than the notice of appeal, must include a statement that one copy of the materials has been sent to the other party, identifying when and to whom the copy was sent.
- (d) Unless hand delivered, all materials should be sent to the Board and the other party by certified or registered mail, return receipt requested.
- (e) The Board considers material to be submitted on the date when it is postmarked or hand delivered to the Board.

*[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]*

• **§ 16.21 Record and decisions.**

- (a) Each decision is issued by three Board members (see § 16.5(b)), who base their decision on a record consisting of the appeal file; other submissions of the parties; transcripts or other records of any meetings, conferences or hearings conducted by the Board; written statements resulting from conferences; evidence submitted at hearings; and orders and other documents issued by the Board. In addition, the Board may include other materials (such as evidence submitted in another appeal) after the parties are given notice and an opportunity to comment.
- (b) The Board will promptly notify the parties in writing of any disposition of a case and the basis for the disposition.

• **§ 16.22 The effect of an appeal.**

- (a) **General.** Until the Board disposes of an appeal, the respondent shall take no action to implement the final decision appealed.
- (b) **Exceptions.** The respondent may—
  - (1) Suspend funding (see § 75.371 of this title);
  - (2) Defer or disallow other claims questioned for reasons also disputed in the pending appeal;
  - (3) In programs listed in appendix A, B.(a)(1), implement a decision to disallow Federal financial participation claimed in expenditures reported on a statement of expenditures, by recovering, withholding or offsetting payments, if the decision is issued before the reported expenditures are included in the calculation of a subsequent grant; or
  - (4) Take other action to recover, withhold, or offset funds if specifically authorized by statute or regulation.

*[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]*

• **§ 16.23 How long an appeal takes.**

The Board has established general goals for its consideration of cases, as follows (measured from the point when the Board receives the first submission after the notice of appeal):

- For regular review based on a written record under § 16.8, 6 months. When a conference under § 16.10 is held, the goal remains at 6 months, unless a requirement for post-conference briefing in a particular case renders the goal unrealistic.
- For cases involving a hearing under § 16.11, 9 months.
- For the expedited process under § 16.12, 3 months.

These are goals, not rigid requirements. The paramount concern of the Board is to take the time needed to review a record fairly and adequately in order to produce a sound decision. Furthermore, many factors are beyond the Board's direct control, such as unforeseen delays due to the parties' negotiations or requests for extensions, how many cases are filed, and Board resources. On the other hand, the parties may agree to steps which may shorten review by the Board; for example, by waiving the right to submit a brief, by agreeing to shorten submission schedules, or by electing the expedited process.

## Appendix A to Part 16—What Disputes the Board Reviews

### A. What this appendix covers.

This appendix describes programs which use the Board for dispute resolution, the types of disputes covered, and any conditions for Board review of final written decisions resulting from those disputes. Disputes under programs not specified in this appendix may be covered in a program regulation or in a memorandum of understanding between the Board and the head of the appropriate HHS operating component or other agency responsible for administering the program. If in doubt, call the Board. Even though a dispute may be covered here, the Board still may not be able to review it if the limits in paragraph F apply.

### B. Mandatory grant programs.

- (a) The Board reviews the following types of final written decisions in disputes arising in HHS programs authorizing the award of mandatory grants:
  - (1) Disallowances under Titles I, IV, VI, X, XIV, XVI(AABD), XIX, and XX of the Social Security Act, including penalty disallowances such as those under sections 403(g) and 1903(g) of the Act and fiscal disallowances based on quality control samples.
  - (2) Disallowances in mandatory grant programs administered by the Public Health Service, including Title V of the Social Security Act.
  - (3) Disallowances in the programs under sections 113 and 132 of the Developmental Disabilities Act.
  - (4) Disallowances under Title III of the Older American Act.
  - (5) Decisions relating to repayment and withholding under block grant programs as provided in 45 CFR 96.52.
  - (6) Decisions relating to repayment and withholding under State Legalization Impact Assistance Grants as provided in 45 CFR 402.24 and 402.25.
- (b) In some of these disputes, there is an option for review by the head of the granting agency prior to appeal to the Board. Where an appellant has requested review by the agency head first, the "final written decision" required by § 16.3 for purposes of Board review will generally be the agency head's decision affirming the disallowance. If the agency head declines to review the disallowance or if the appellant withdraws its request for review by the agency head, the original disallowance decision is the "final written decision." In the latter cases, the 30-day period for submitting a notice of appeal begins with the date of receipt of the notice declining review or with the date of the withdrawal letter.

### C. Direct, discretionary project programs.



- (a) The Board reviews the following types of final written decisions in disputes arising in any HHS program authorizing the award of direct, discretionary project grants or cooperative agreements:
- (1) A disallowance or other determination denying payment of an amount claimed under an award, or requiring return or set-off of funds already received. This does not apply to determinations of award amount or disposition of unobligated balances, or selection in the award document of an option for disposition of program-related income.
  - (2) A termination for failure to comply with the terms of an award.
  - (3) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.
  - (4) A voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).
- (b) Where an HHS component uses a preliminary appeal process (for example, the Public Health Service), the "final written decision" for purposes of Board review is the decision issued as a result of that process.

*D. Cost allocation and rate disputes.*

The Board reviews final written decisions in disputes which may affect a number of HHS programs because they involve cost allocation plans or rate determinations. These include decisions related to cost allocation plans negotiated with State or local governments and negotiated rates such as indirect cost rates, fringe benefit rates, computer rates, research patient care rates, and other special rates.

*E. SSI agreement disputes.*

The Board reviews disputes in the Supplemental Security Income (SSI) program arising under agreements for Federal administration of State supplementary payments under section 1616 of the Social Security Act or mandatory minimum supplements under section 212 of Pub. L. 93-66. In these cases, the Board provides an opportunity to be heard and offer evidence at the Secretarial level of review as set out in the applicable agreements. Thus, the "final written decision" for purposes of Board review is that determination appealable to the Secretary under the agreement.

*F. Where Board review is not available.*

The Board will not review a decision if a hearing under 5 U.S.C. 554 is required by statute, if the basis of the decision is a violation of applicable civil rights or nondiscrimination laws or regulations (for example, Title VI of the Civil Rights Act), or if some other hearing process is established pursuant to statute.

*G. How the Board determines whether it will review a case.*

Under § 16.7, the Board Chair determines whether an appeal meets the requirements of this appendix. If the Chair finds that there is some question about this, the Board will request the written opinion of the HHS component which issued the decision. Unless the Chair determines that the opinion is clearly erroneous, the Board will be bound by the opinion. If the HHS component does not respond within a time set by the Chair, or cannot determine whether the Board clearly does or does not have jurisdiction, the Board will take the appeal.

[46 FR 43817, Aug. 31, 1981, as amended at 47 FR 29492, July 6, 1982; 53 FR 7864, Mar. 10, 1988; 62 FR 38218, July 17, 1997]

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

STATE OF OHIO, <i>et al.</i> ,	:	Case No. 1:21-cv-675
Plaintiffs,	:	
	:	Judge Timothy S. Black
vs.	:	
	:	
XAVIER BECERRA, <i>et al.</i> ,	:	
Defendants.	:	

**ORDER DENYING PLAINTIFFS' MOTION  
FOR A PRELIMINARY INJUNCTION**

This civil case is before the Court on Plaintiffs' Motion for Preliminary Injunction (Doc. 2), Defendants' memorandum in opposition (Doc. 27), and Plaintiffs' reply (Doc. 46).<sup>1</sup> Plaintiffs seek an order preliminarily enjoining the Department of Health and Human Services ("the Department," or "HHS") from implementing or enforcing the final rule, *Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services*, 86 Fed. Reg. 56144-01 (Oct. 7, 2021) (to be codified at 42 C.F.R. pt. 59) ("the Final Rule"). The Final Rule effectively re-adopts HHS's 2000 Rule by eliminating strict physical and financial separation between Title X services and abortion services and by requiring nondirective pregnancy counseling and referrals for abortion services when requested. Because the Court finds Plaintiffs unlikely to succeed

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<sup>1</sup> The Court has also received and considered, with appreciation, four briefs of amicus curiae: one from Montana, Georgia, Idaho, Indiana, Louisiana, Mississippi, South Dakota, and Texas supporting Plaintiffs, (Doc. 22); one from California, New York, Colorado Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, Wisconsin, and the District of Columbia supporting HHS, (Doc. 28); one from Planned Parenthood Federation of America, Inc. supporting HHS, (Doc. 31); and one from National Family Planning & Reproductive Health Association (Doc. 33).

on the merits of their APA claim, that the Plaintiff states will not be irreparably harmed when the Final Rule becomes effective, and that enjoining the Final Rule would perpetuate well-documented harm to the public, the Court **DENIES** injunctive relief to Plaintiffs.

## I. BACKGROUND

This case is a straightforward application of administrative law to Title X of the *Family Planning Services & Population Research Act of 1970*, Pub. L. No. 91-572, 84 Stat. 1504 (1970), codified at 42 U.S.C. §§ 300 *et seq.* (“Title X” or “the Act”). In 1970, Congress enacted Title X to provide federal funding for family planning services. The statute authorizes the Secretary of the Department of Health and Human Services to promulgate regulations for the distribution of Title X grants. *Id.* at § 300. Title X expressly requires that “priority will be given” to projects that provide family planning services to “persons from low-income families,” *id.* at § 300a-4, and that funded projects must “offer a broad range of acceptable and effective family planning methods and services,” *Id.* In Section 1008 of Title X, however, Congress qualified that “[n]one of the funds appropriated under this subchapter shall be used in **programs** where abortion is a method of family planning.” *Id.* at § 300a-6 (emphasis supplied). This language is at the heart of this dispute.

For roughly the first 18 years of Title X’s history, participating providers could offer non-directive pregnancy counseling including referrals for abortion at the patient’s

request.<sup>2</sup> The regulations implementing Title X merely required grant applicants to provide “[a]ssurances that ... [t]he project w[ould] not provide abortions as a method of family planning.” *Project Grants for Family Planning Services*, 36 Fed. Reg. 18,465, 18,466 (Sept. 15, 1971).

Then, in 1988, HHS issued regulations that barred providers from referring patients for abortion services or offering them any abortion-related information, and required providers to refer patients to prenatal care regardless of their patients’ wishes. *Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects*, 53 Fed. Reg. 2,922, 2,927 (Feb. 2, 1988). The 1988 Rule further required physical and financial separation between Title X-funded services and any abortion-related services. *Id.* The 1988 Rule did not, however, purport to extend its restrictions beyond the “Title X-funded ‘program’ or ‘project.’” *Id.* at 2927. HHS found “read[ing] the term ‘program’ in section 1008 as relating to the funded organization as a whole” was “not supportable.” *Id.* The 1988 Rule was immediately challenged in court and was therefore never fully effective nationwide. *See Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,270, 41,271

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<sup>2</sup> See Mem. from Carol C. Conrad, Off. of the Gen. Couns., Dep’t of Health, Educ. & Welfare, to Elsie Sullivan, Assistant for Info. & Educ., Off. of Family Planning, BCHS (Apr. 14, 1978) (“[T]he provision of information concerning abortion services, mere referral of an individual to another provider of services for an abortion, and the collection of statistical data and information regarding abortion are not considered to be proscribed by § 1008.”) (cited by *Family Planning Ass’n of Me. v. HHS*, 404 F. Supp. 3d 286, 292 n.7 (D. Me. 2019)); *Standards of Compliance for Abortion-Related Services in Family Planning Service Projects*, 58 Fed. Reg. 7464, 7464 (Feb. 5, 1993).

(July 3, 2000).

In 1991, the Supreme Court upheld the 1988 Rule. *Rust v. Sullivan*, 500 U.S. 173 (1991). Petitioners in *Rust* argued that Congress did not intend strict financial and physical separation, nor did Congress intend to ban referrals for abortion-related services where patients requested one. *Id.* at 184, 189. In rejecting petitioners' arguments, the Court held that Section 1008's legislative history was "ambiguous," and thus permitted multiple interpretations. The Supreme Court observed that petitioners' interpretation "may [have] be[en] a permissible one," but it was "by no means the only one" and "not the one found by the Secretary." *Id.* at 189. Thus, the Court accorded the interpretation on which the 1988 Rule was based "substantial deference." *Rust*, 500 U.S. at 184.

Where they *were* in effect, the 1988 Rules did not last long. In February 1993, President William Clinton directed HHS to rescind the 1988 Rules and return to the "compliance standards that were in effect prior to the issuance of the [1988 Rules]." *The Title X "Gag Rule,"* 58 Fed. Reg. 7,455 (Jan. 22, 1993); *Standards of Compliance for Abortion-Related Services in Family Planning Service Projects*, 58 Fed. Reg. 7,462 (Feb. 5, 1993) (interim rule). HHS simultaneously issued a notice of proposed rulemaking. *Standards of Compliance for Abortion-Related Services in Family Planning Service Projects*, 58 Fed. Reg. 7,464 (notice of proposed rule).

Starting in 1996, Congress added a rider to its annual HHS appropriations act that stated: "[A]mounts provided to [Title X] projects ... shall not be expended for abortions, [and] all pregnancy counseling shall be nondirective." *Omnibus Consolidated Rescissions and Appropriations Act of 1996*, Pub. L. No. 104-134, 110 Stat. 1321, 1321-221 (Apr.



26, 1996). An identical rider has appeared in every annual HHS appropriations bill since 1996. *See, e.g., Consolidated Appropriations Act, 2021*, Pub. L. No. 116-260, 134 Stat 1182 (Dec. 27, 2020).

After considering the interim rule for nearly seven years, HHS released the final version in July 2000. *Standards of Compliance for Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,270, 41,271 (July 3, 2000). The 2000 Rule mostly “readopt[ed] the regulations ... that applied to [Title X] prior to February 2, 1988.” *Id.* It permitted referrals for abortion services at the patient’s request. *Id.* at 41,274. It also rejected the strict financial and physical separation requirements from the 1988 Rule. *Id.* at 41,275-76. HHS concluded that those requirements were “unenforceable” and inconsistent “with the efficient and cost-effective delivery of family planning services.” *Id.* at 41,275-76. Simultaneously, HHS published notice of its interpretations of Section 1008’s requirements. *Provision of Abortion-Related Services in Family Planning Services Projects*, 65 Fed. Reg. 41,281 (Jul. 3, 2000). The notice clarified that Section 1008’s prohibition on “funds ... used in a program where abortion is a method of family planning” “does not apply to all the activities of a Title X grantee, but only to those within the Title X project.” *Id.* at 41,281. HHS defined “Title X project” as the “set of activities the grantee agreed to perform ... as a condition of receiving Title X funds.” *Id.* The notice warned that “[m]ere technical allocation of funds, attributing federal dollars to non-abortion activities,” does not comply with Section 1008. By way of illustration, HHS elaborated that:

Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities: (a) A common waiting room is permissible, as long as the costs [are] properly pro-rated; (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project. (c) a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project; and (d) maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated.

*Id.* at 41,282. **The 2000 Rule remained in effect, unchallenged, for more than 18 years.**

Then, in 2019, under the Trump administration, HHS promulgated a new final rule reinterpreting Section 1008. *Compliance with Statutory Program Integrity Requirements*, 85 Fed. Reg. 7,714, 7,722-77 (Mar. 4, 2019). The 2019 Rule reinstated the 1988 Rule's requirements for strict physical and financial separation citing the "fungibility of Title X resources." *Id.* It eliminated the requirement for nondirective pregnancy counseling (*i.e.*, counselling that is not designed to direct a patient towards either prenatal care or termination) citing federal conscience laws. *Id.* at 7,716. And it prohibited referrals for abortion because, in the Department's view, "referral necessarily treats abortion as a method of family planning." *Id.* at 7,717. HHS predicted that these changes would "contribute to more clients being served," and that "new applicants w[ould] apply to serve unserved or underserved patients and/or less concentrated population areas," and further that "new providers who previously were unable to participate in Title X projects

due to conscience concerns with the 2000 regulations w[ould] be free to apply for a Title X grant or to participate in a Title X project.” *Id.* at 7,723.

This prediction proved wishful. Shortly after the 2019 Rule took effect, the number of Title X grantees cratered. According to HHS:

After the implementation of the 2019 Title X Final Rule, 19 Title X grantees out of 90 total grantees, 231 subrecipients, and 945 service sites immediately withdrew from the Title X program. Overall, the Title X program lost more than 1,000 service sites. Those service sites represented approximately one quarter of all Title X-funded sites in 2019. Title X services are not currently available at all in six states (HI, ME, OR, UT, VT, and WA) and are only available on a very limited basis in six additional states (AK, CT, MA, MN, NH, and NY). California, the single-largest Title X project in the nation (before the 2019 Final Rule) had 128, or 36 percent, of its Title X service sites withdraw from the program, leaving more than 700,000 patients without access to Title X-funded care. Similarly, in New York, the number of Title X-funded service sites dropped from 174 to just two, leaving more than 328,000 patients without Title X-funded care. All Planned Parenthood affiliates—which in 2015 had served 41 percent of all clients at Title X service sites—withdraw from Title X due to the 2019 Final Rule.

*Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning*

*Services*, 86 Fed. Reg. 19,812, 19,815 (April 15, 2021). The Office of Population Affairs

(“OPA”), the office which administers Title X within HHS, estimates that **the 2019 Rule**

**caused 1.5 million fewer patients to participate in Title X-funded services between**

**2019 and 2020.** Christina Fowler et al., *Title X Family Planning Annual Report: 2020*

*National Summary*, OPA, 25 (Sept. 2021), [https://opa.hhs.gov/sites/default/files/2021-](https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf)

[09/title-x-fpar-2020-national-summary-sep-2021.pdf](https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf).

The Department's efforts to reverse this trend were unavailing. When the withdrawn Title X grantees relinquished their funding, HHS distributed \$33.6 million dollars of relinquished funds to 50 Title X grantees. *Press Release, HHS, HHS Issues Supplemental Grant Awards to Title X Recipients* (Sept. 30, 2019), <https://opa.hhs.gov/about/news/grant-award-announcements/hhs-issues-supplemental-grant-awards-title-x-recipients>. The Department "expect[ed] the supplemental awards w[ould] enable grantees to come close to—if not exceed—prior Title X patient coverage." *Id.* But by the end of 2019, OPA estimated that Title X had served 21% fewer patients (844,083 users) than in 2018.

Dozens of states challenged the rule.<sup>3</sup> District Courts for the District of Maryland,<sup>4</sup> the Eastern District of Washington,<sup>5</sup> the District of Oregon,<sup>6</sup> and the Northern District of California<sup>7</sup> granted preliminary injunctions. Sitting en banc, the Court of Appeals for the Ninth Circuit, vacated three of the preliminary injunctions. *See California by & through Becerra v. Azar*, 950 F.3d 1067 (9th Cir. 2020). The Court of Appeals for the Fourth Circuit, also en banc, disagreed with the Ninth Circuit. *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020). Noting "the Ninth Circuit did not have

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<sup>3</sup> Washington, Oregon, New York, Colorado, Connecticut, Delaware, District of Columbia, Hawai'i, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Pennsylvania, Rhode Island, Vermont, and Virginia.

<sup>4</sup> *Mayor & City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602 (D. Md. 2019).

<sup>5</sup> *Washington v. Azar*, 376 F. Supp. 3d 1119 (E.D. Wash. 2019).

<sup>6</sup> *Oregon v. Azar*, 389 F. Supp. 3d 898 (D. Or. 2019).

<sup>7</sup> *State v. Azar*, 385 F. Supp. 3d 960 (N.D. Cal. 2019).

the full administrative record before it,” the Fourth Circuit affirmed the Maryland court’s ruling that the 2019 Rule was arbitrary and capricious, and upheld the lower court’s permanent injunction of the 2019 Rule in the state of Maryland. *Mayor of Baltimore*, 392 F. Supp. 3d at 280, 295.

On February 22, 2021, the Supreme Court granted certiorari and consolidated the appeals from the Ninth and Fourth Circuits. *Oregon v. Cochran*, 141 S. Ct. 1369 (2021). But on March 12, 2021, the parties voluntarily dismissed the cases. *See Am. Med. Assn. v. Becerra*, 141 S. Ct. 2170 (2021).

On October 7, 2021, HHS published a new final rule interpreting Section 1008, (“the Final Rule”). Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 FR 56,144-01 (Oct. 7, 2021). **The Final Rule effectively re-adopts the 2000 Rule by eliminating strict physical and financial separation between Title X services and abortion services and by requiring nondirective pregnancy counseling and referrals for abortion services when requested.** *Id.* at 56,144. In response, some former Title X grantees have already mobilized to return to the program, either as sub-grantees<sup>8</sup> or by submitting applications to return to return as primary grantees.<sup>9</sup>

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<sup>8</sup> See, e.g., Bacharier, *Planned Parenthood’s Springfield, Joplin Clinics to Rejoin Federal Grant Program after Trump Rule Reversed*, Springfield News-Leader (Oct. 22, 2021), <https://www.newsleader.com/story/news/politics/2021/10/22/springfield-joplin-mo-planned-parenthood-rejoins-federal-program-titlex-after-trump-rule-reversed/6119400001/>

<sup>9</sup> See Doc. 31-1 at 19; HHS, *Funding to Address Dire Need for Family Planning Services* (Nov. 10, 2021), <https://www.grants.gov/web/grants/view-opportunity.html?oppId=335742>; Dep’t Health & Human Servs., *Title X Family Planning Services Grants* (Oct. 27, 2021), <https://www.grants.gov/web/grants/view-opportunity.html?oppId=334698>.



Plaintiffs, 12 states represented by their attorneys general, now seek to preliminarily enjoin the Final Rule under the Administrative Procedure Act (“the APA”). They argue that the Final Rule is “arbitrary and capricious” and/or “otherwise not in accordance with law.” 5 U.S.C. § 706(2). They are wrong on both counts. And because the available record establishes that Plaintiffs are unlikely to succeed on their APA claims,<sup>10</sup> Plaintiffs’ motion for a preliminary injunction is **DENIED**.

## II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 65 empowers district courts to issue preliminary injunctions “to preserve the status quo so that a reasoned resolution of a dispute may be had.” *Procter & Gamble Co. v. Bankers Trust Co.*, 78 F.3d 219, 227 (6th Cir. 1996). Courts consider four factors: “(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury without the injunction; (3) whether issuance of the injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of the injunction.” *City of Pontiac Retired Emps. Ass’n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (per curiam) (en banc). Where the federal government is the defendant, the third and fourth factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). In the Sixth Circuit, “[t]hese factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together.” *Commonwealth v. Beshear*, 981 F.3d 505, 508 (6th Cir. 2020).

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<sup>10</sup> The parties in this lawsuit have stipulated that the Court may adjudicate Plaintiffs’ motion for a preliminary injunction without submission of Defendants’ certified administrative record. (Doc. 20). See *California v. Azar*, 950 F.3d 1067, 1083 & n.11 (9th Cir. 2020) (en banc) (explaining that courts may rule on preliminary injunction motions before administrative record is completed where doing so is not unfair to either party).

That said, “the existence of an irreparable injury is mandatory,” such that “even the strongest showing on the other three factors cannot eliminate the irreparable harm requirement.” *D.T. v. Sumner Cnty. Schs.*, 942 F.3d 324, 326-27 (6th Cir. 2019).

A preliminary injunction is an “**extraordinary remedy** involving the exercise of a very far-reaching power, which is to be applied only in the limited circumstances which clearly demand it.” *Leary v. Daeschner*, 228 F.3d 729, 739 (6th Cir. 2000).

Accordingly, **a party seeking an “injunction must establish its case by clear and convincing evidence.”** *Honeywell, Inc. v. Brewer–Garrett Co.*, 145 F.3d 1331 (6th Cir. 1998) (emphasis supplied).

### III. ANALYSIS

#### 1. Plaintiffs are not likely to win their challenges under the APA

On the merits, Plaintiffs argue that the Court should block the Final Rule under the Administrative Procedure Act (the “APA”). The APA requires that courts “hold unlawful and set aside agency action[s]” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. §706(2)(A). Plaintiffs assert the Final Rule is (1) “not in accordance” with Section 1008 and (2) “arbitrary and capricious.”

##### a. The Final Rule is entitled to *Chevron* deference

Plaintiffs assert that the Final Rule contravenes Section 1008 of Title X by eliminating strict financial and physical separation requirements, and requiring referrals for abortion services where requested. To review, Section 1008 states, in its entirety:

None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.

42 U.S.C. § 300a-6.

In determining whether to uphold an agency’s regulation implementing a federal statute, courts apply the “familiar two-step test pursuant to *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).” *Mayor of Baltimore v. Azar*, 973 F.3d 258, 268 (4th Cir. 2020). On Step One, a court asks “whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Chevron*, 467 U.S. at 842-43. Alternatively, “[i]f the statute is silent or ambiguous with respect to the specific issue,” the court proceeds to Step Two where “the question for the court is whether the agency’s answer is based on a permissible construction of the statute.” *Id.* at 843.

In this case, both parties agree that *Chevron* applies to the Department’s interpretation of Section 1008 underlying the Final Rule. Plaintiffs further concede, as they must, that the Supreme Court in *Rust* declared Section 1008 “ambiguous.” *See* Doc. 2 at 13; *Rust*, 500 U.S. at 184. Specifically, the Supreme Court in *Rust* held:

[W]e agree with every court to have addressed the issue that the language is ambiguous. The language of § 1008—that “[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning”—does not speak directly to the issues of counseling, referral, advocacy, or program integrity.

*Id.* The Supreme Court then quoted the lower court opinions that it agreed with, including the First Circuit’s pronouncement that “[t]he language of the statute and the

legislative history can support either of the litigants' positions." *Id.* at 185 (citing *Com. of Mass. v. Sec'y of Health & Hum. Servs.*, 899 F.2d 53, 62 (1st Cir. 1990)). The Supreme Court's holding in *Rust* is binding on this Court. Plaintiffs' citations to the pronouncements of specific legislators (Doc. 2 at 3-4) are therefore gratuitous and irrelevant.

Because the Supreme Court has already held that Section 1008 is ambiguous, this Court's review of the Final Rule may skip ahead to *Chevron* Step Two. On Step Two, "the question for the court is whether the agency's [rule] is based on a *permissible* construction of the statute." *Chevron*, 467 U.S. at 843 (emphasis supplied). Traditionally, on Step Two, courts followed the Supreme Court's direction that "that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Id.* at 844. This **high degree of deference** follows from the Court's preference that, "in the context of implementing policy decisions a technical and complex arena, ... policy arguments are more properly addressed to legislators or administrators, not judges." *Id.* at 864-65. "Judges are not experts in the field" of energy policy (as in *Chevron*) or healthcare policy (as in this case).

Nor are judges "part of either political branch of the Government." *Id.* at 865. Though agencies may not be "directly accountable to the people, the Chief Executive is." *Id.* Thus, as held by the Supreme Court, an agency may "properly rely upon the incumbent administration's views of wise policy to inform its judgments," where a court may not. *Id.*

A final reason for *Chevron* deference recognizes that, in some statutes, Congress may have *intended* ambiguity. Courts may “accord deference to agencies under *Chevron* ... because of a presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows.” *Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 740–41 (1996) (Scalia, J.).

*Chevron* deference applies equally where an “agency has from time to time changed its interpretation.” *Id.* at 863. An agency “must consider varying interpretations and the wisdom of its policy on a continuing basis. Moreover, the fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly [where] Congress has never indicated any disapproval of a flexible reading of the statute.” *Id.* at 863-64.

**This case features all of the reasons to defer to HHS’s interpretation of Section 1008.** To preview the Court’s discussion below, Section 1008 involves technical and complex decisions about healthcare policy; the Final Rule was obviously and properly a response to shifting political winds; and the ambiguous language of Section 1008, as Plaintiffs eagerly point out, was likely the intentional result of legislative compromise. Accordingly, the Final Rule is entitled to *Chevron* deference. Therefore, to demonstrate a strong likelihood of success on the merits of their APA claim, Plaintiffs must show that the Final Rule is not a “permissible construction” of Section 1008. Plaintiffs make two arguments on that score. *First*, they assert that the Final Rule is “not



in accordance with law,” *i.e.*, Section 1008. 5 U.S.C. § 706(2)(A). *Second*, Plaintiffs argue that the Final Rule is “arbitrary and capricious.” *Id.*

**i. Plaintiffs are unlikely to demonstrate that the Final Rule is not in accordance with Section 1008**

Plaintiffs first argue that the Final Rule rests on an interpretation of Section 1008 that is “impermissible” because it is “not in accordance with” Section 1008. The Court is not aware of authority that permits it to merge “permissibility” under *Chevron* with “accordance with law” under the APA.<sup>11</sup> The parties, however, seem content to treat them the same, so, for the purposes of this Order, the Final Rule is “in accordance with” Section 1008, (5 U.S.C. § 706(2)(A)), if it is a “permissible construction” of Section 1008, (*Chevron*, 467 U.S. at 843).

*First*, Plaintiffs assert that Section 1008 prohibits the degree of financial and physical integration between Title X programs and abortion service providers permitted in the Final Rule. Under the Final Rule:

Non-Title X abortion activities must be separate and distinct from Title X project activities. Where a grantee conducts abortion activities that are not part of the Title X project and would not be permissible if they were, the grantee must ensure that the Title X-supported project is separate and distinguishable from those other activities. What must be looked at is whether the abortion element in a program of family planning services is so large and so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost.

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<sup>11</sup> Although the Sixth Circuit has suggested that “permissible under *Chevron*” is a distinct inquiry from the requirements under the APA, that case only addressed the distinction between “permissible” and “arbitrary and capricious.” *Atrium Med. Ctr. v. U.S. Dep’t of Health & Hum. Servs.*, 766 F.3d 560, 567 (6th Cir. 2014)

65 Fed. Reg. at 41,282 (incorporated by reference at 86 Fed. Reg. at 56150).

The Final Rule further clarifies that:

Separation of Title X from abortion activities does not require separate grantees or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008.

Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities: (a) A common waiting room is permissible, as long as the costs properly pro-rated; (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project; (c) a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project; and (d) maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated.

*Id.* Therefore, Plaintiffs argue, the Rule permits grantees to have an “abortion element” which contravenes the statute’s prohibition on grants “used in programs where abortion is a method of family planning.” 42 U.S.C. § 300a-6.

**Plaintiffs’ argument elides the distinction between a Title X “grantee” and a Title X “program” or “project.”**<sup>12</sup> Title X “expressly distinguishes between a Title X *grantee* and a Title X *project*.” *Rust*, 500 U.S. at 196. While a grantee “may receive funds from a variety of sources for a variety of purposes,” the grantee’s Title X funds are

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<sup>12</sup> The terms “program” and “project” were used interchangeably in both the 2019 and 1988 Rules. *See* 84 Fed. Reg. at 7787; 53 Fed. Reg. at 2922.

reserved for the “specific and limited purpose of establishing and operating a Title X project.” *Id.* (citing 42 U.S.C. § 300(a)). Thus, a Title X program may offer less than the full menu of family planning services without bringing off-menu services into the program.

The Supreme Court specifically approved of this possibility in *Rust*. 500 U.S. at 196. Concluding that the 1988 Rule did not impermissibly condition grant awards on “relinquishment of a constitutional right,” the Court found that a “Title X *grantee* can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy” as long as it “conduct[s] those activities through programs that are separate and independent from the project that receives Title X funds.” *Id.* (emphasis in original). Because the Final Rule expressly prohibits abortion-related services from being a part of a grantee’s Title X *program*, the Court finds Plaintiffs’ argument unpersuasive.<sup>13</sup>

Next, Plaintiffs argue that the Final Rule’s permission to share staff, waiting rooms, and file systems is impermissible because it allows Title X funds to be used “in a program *where* abortion is a method of family planning”—emphasizing that “where” refers to a “physical location.” (Dec. 2 at 15). This is not a serious argument. “Where” need not refer to a physical location.<sup>14</sup> Plaintiffs point to nowhere in the legislative

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<sup>13</sup> An alternative interpretation of Plaintiffs’ argument is that the phrase, “abortion element in a program of family planning services,” presumes that a *Title X program* may have an “abortion element.” 65 Fed. Reg. at 41282. While the Court acknowledges that the Department’s choice of the word “program” is unfortunate, reading the passage with full context reassures that the Final Rule does not permit an abortion element in a “Title X program.” *See id.* (“Non-Title X abortion activities must be separate and distinct from Title X project activities.”).

<sup>14</sup> Where, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/where> (defining “where” as “at, in, or to what situation, position, direction, circumstances, or respect”).

history suggesting Congress meant otherwise.

Last, Plaintiffs argue that the Final Rule is “not in accordance with” Section 1008 because removing strict physical and financial separation requirements permits Title X funds to impermissibly “subsidize” abortion activities. The way this works, according to Plaintiffs, is that, because “[m]oney is fungible,” “every dollar an abortion provider receives through Title X frees up another dollar that the grantee can use to subsidize abortion.” (Doc. 2 at 16) (citing *Holder v. Humanitarian Law Project*, 561 U.S. 1, 31 (2010)).

Unfortunately for Plaintiffs, “fungible” is not the magic word they wish it were. True, money is fungible. But strict financial and physical separation does not make it any less fungible. By Plaintiffs’ logic, even the 2019 Rule permitted Title X funds to subsidize abortions. Under that rule, abortion providers could still receive Title X grants so long as they could comply with the physical and financial separation requirements. *Rust*, 500 U.S. at 199 n.5 (noting that regulations implementing Section 1008 “are limited to Title X funds; the recipient remains free to use private, non-Title X funds to finance abortion-related activities.”); *see also, e.g., Planned Parenthood of Hous. & Se. Tex. v. Sanchez*, 403 F.3d 324, 340 (5th Cir. 2005) (“Under Title X, then, abortion providers are eligible to receive family planning funding.”); *Planned Parenthood of Cent. N.C. v. Cansler*, 804 F. Supp. 2d 482, 487 (M.D.N.C. 2011) (“[T]itle X does not contain any provision that would prohibit entities that provide abortions from receiving Title X funds for non-abortion-related services.”). Therefore, under the 2019 Rule, a hypothetical family planning service provider with two physical clinics, distinct staff at each location,

separate accounting records for each, and a \$100,000 overall budget might provide \$50,000 of services at each location. If the same provider received a \$100,000 Title X grant to run one clinic as a Title X program, that grant would “free up” \$100,000 to be spent on abortion services at the other clinic. Because demand for family planning and abortion services is finite, money is equally fungible across entities too. Every grant dollar spent providing contraceptive services at a Title X program, for example, is a dollar a Planned Parenthood affiliate did not have to spend servicing the same patient.

These examples illustrate that Plaintiffs’ reasoning is untenable. It leads, ineluctably, to the conclusion that abortion-providers may not participate in Title X. That may be Plaintiffs’ true motivation, but it is not the law. *Rust*, 500 U.S. at 199. Indeed, courts have rejected the “freeing up” theory in the context of abortion funding. *See Planned Parenthood of Cent. & N. Arizona v. State of Ariz.*, 718 F.2d 938, 945 (9th Cir. 1983), *aff’d sub nom. Babbitt v. Planned Parenthood of Cent. & N. Arizona*, 479 U.S. 925 (1986) (“[W]e hold that as a matter of law, the freeing-up theory cannot justify withdrawing all state funds from otherwise eligible entities merely because they engage in abortion-related activities disfavored by the state.”); *see also Planned Parenthood of Minn. v. Minnesota*, 612 F.2d 359, 362 (8th Cir. 1980) (rejecting “[t]he argument that the money given to Planned Parenthood by the state might free-up other money which would be used for abortions”). Accordingly, the Court is not persuaded that eliminating the strict financial and physical separation requirements from the 2019 Rule impermissibly “subsidizes abortions.” **The principle that money is fungible must have theoretical limits or else no government appropriations for specific purposes could ever be**



**feasible. Title X no more subsidizes abortions than funding a homeless shelter subsidizes substance abuse.** Plaintiffs are therefore not likely to succeed on their claim that the Final Rule is impermissible because eliminating the separation requirements violates Section 1008.

Plaintiffs also assert that the Final Rule violates Section 1008 by requiring grantees to provide “information and counseling” and “referral” for abortion services upon request. 86 Fed. Reg. at 56,170. Plaintiffs reason that a family planning program in which providers are required to make referrals for abortion upon request is a program “where abortion is a method of family planning” in violation of Section 1008. (Doc. 2 at 17). Plaintiffs’ argument proceeds by analogy. They ask, for example, “Is a dental practice that refers patients to its own doctors for root canals a practice where root canals are a method of dental care?” (Doc. 2 at 18). But again, Plaintiffs muddy the distinction between a “grantee” and a “program.” A “program” may provide less than the full gamut of healthcare services that a “grantee” would offer. To take Plaintiffs’ analogy head on: a dental practice that provides free teeth cleanings at a weekend clinic could decline to provide costly root canals as part of the program. But a dentist could refer a patient to her own commercial practice for paid services during the week and no one could argue that root canals were a part of the weekend clinic program. Simply put, root canals are indisputably a dental service, but they are not part of the menu of low-cost services offered at the weekend clinic program. Likewise, abortion *is*, literally-speaking, a method of family planning. But it is simply not part of the menu of family planning services that a Title X program can offer. Providing a referral for it does not put it on the

menu. Therefore, because the *program* provides less than the full menu of treatment options at a reduced cost, referrals for services outside of the program do not contravene Section 1008. The Court is not persuaded, based on Plaintiffs’ analogies, that Plaintiffs are likely to succeed on their argument that the Final Rule’s referral mandate is “not in accordance” with Section 1008.

**b. Plaintiffs are unlikely to demonstrate that the Final Rule is arbitrary and capricious**

The APA instructs courts to vacate agency action that is arbitrary and capricious. 5 U.S.C. § 706(2). In general, an agency’s action is arbitrary and capricious where it has “relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Nat’l Ass’n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 658 (2007). Final rules must therefore “articulate a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983). Agencies are not, however, required to consider all policy alternatives “conceivable by the mind of man” in reaching a decision. *Id.* at 51.

“When an agency changes its existing position, it need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate.” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016). The agency need only

“display awareness that it is changing position” and “show that there are good reasons for the new policy.” *Id.* An agency changing “longstanding policies,” should take into account “serious reliance interests.” *Id.*

Arbitrary and capricious is a “deferential” standard. *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The “court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision.” *Id.* **A court’s review is “narrow” and “is not to substitute its judgment for that of the agency.”** *State Farm*, 463 U.S. at 43 (emphasis supplied).

Plaintiffs argue (unsuccessfully) that the Final Rule’s “approach to financial and physical separation” and its requirement that providers make abortion referrals upon request are arbitrary and capricious.

**i. HHS reasonably revoked the 2019 Rule’s physical and financial separation requirements**

Plaintiffs advance four arguments to support to support their theory that the Final Rule arbitrarily and capriciously rescinded the 2019 Rule’s financial and physical separation requirements. *First*, Plaintiffs reiterate their argument that the Final Rule does not prevent Title X funds from subsidizing abortion in violation of Section 1008. *Second*, Plaintiffs allege HHS relied on “flaw data and illogical reasoning” to conclude that the 2019 Rule had negative health consequences. *Third*, Plaintiffs accuse HHS of overlooking “important reliance interests” in promulgating the final rule. And *fourth*,

Plaintiffs claim HHS should have considered the Final Rule’s effect on “public support for Title X.” These arguments grasp at straws. None are persuasive.

*First*, HHS did properly address fears that Title X funds would be used to subsidize abortions. In the first section of the Notice of Final Rulemaking (“NFR”), HHS described reviewing more than 30 reports from the Government Accountability Office, HHS Office of the Inspector General, and the Congressional Research Service covering the Title X program from 1975 through 2021. 86 Fed. Reg. 56,145. Based on those reports, HHS concluded that, over 45 years, the majority of which time HHS required no strict financial and physical separation, there were only minor compliance issues going back to the 1980s. *Id.* HHS then reasonably weighed the minimal risk of compliance issues absent strict financial and physical separation against the high cost and burden of maintaining separate physical locations, duplicate staff, and separate patient records. *Id.* HHS reasonably concluded, “there has been no evidence of compliance issues regarding section 1008 by Title X grantees that would justify the greatly increased compliance costs for grantees and oversight costs for the federal government the 2019 rule required.” *Id.*

For their part, Plaintiffs are hung up on Department’s “disagree[ment] that Title X grant funds ... are fungible.” *Id.* at 56,150. But HHS’s disagreement clearly meant only that “grant funds are spent for grant purposes.” *Id.* In other words, where the agency provides \$50,000 of Title X funds, the Title X grantee provides \$50,000 of non-abortion related family planning services, and—regardless of what the grantee does with money it gets elsewhere—none of that \$50,000 is spent on abortion-related services. *State Farm*, 463 U.S. at 43 (courts may “uphold a decision of less than ideal clarity if the agency’s

path may reasonably be discerned.”). The logical conclusion of Plaintiffs’ hyperbolic fungibility principle is that any organization that performs abortion would be banned from receiving Title X funds. HHS addressed that too by recognizing that Plaintiffs’ reasoning would “raise serious constitutional issues.” *Id.*

Plaintiffs are also wrong that HHS failed to “consider alternative policies” for keeping Title X funds from subsidizing or promoting abortion. The Final Rule incorporates the interpretations and policies that accompanied the 2000 Rule. *Id.* at 56,150. Those policies require abortion activities to “be separate and distinct from Title X project activities” and demand more than “[m]ere technical allocation of funds.” 65 Fed. Reg. 41,282. HHS further elaborated that “[a]ll Title X grantees are subject to 45 CFR part 75” which requires that Title X funds “be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget” and provides an addition layer of generally applicable agency grant regulations. 86 Fed. Reg. at 56,152. To enforce these requirements, HHS’s Office of Population Affairs (“OPA”) “closely monitors Title X grantee compliance through regular grant reports, compliance monitoring visits, and legally required audits, and it has done so since the beginning of the program.” 86 Fed. Reg. at 56,145. Plaintiffs insist that HHS should have considered additional alternatives such as dedicating additional funds to help with compliance or choosing requirements somewhere between the 2000 Rule’s and the 2019 Rule’s.

But to survive arbitrary and capricious review, agencies are not required to consider every policy alternative “conceivable by the mind of man.” *State Farm*, 463



U.S. at 51; *see also Am. Ass'n of Cosmetology Sch. v. DeVos*, 258 F. Supp. 3d 50, 75 (D.D.C. 2017). HHS met its burden by considering and adopting the 2000-era monitoring and enforcement policies as an alternative to the 2019 separation requirements. The agency's reasoning here is especially persuasive because it can rely on decades of experience using precisely these monitoring and enforcement mechanisms with minimal compliance issues. 86 Fed. Reg. at 56,145.

Plaintiffs, of course, dispute the reliability of the data on compliance issues. This makes sense given that Plaintiffs believe the 2000 Rule permits activities that in fact violate Section 1008. But on review for arbitrary and capricious decision-making, the Court declines to wade into the reliability of reports covering 45 years from three separate federal agencies. **At bottom, Plaintiffs' argument is a policy disagreement about what activities Section 1008 permits.** For reasons stated above, the Court finds the Department's interpretation of Section 1008 permissible and entitled to deference.

*Second*, Plaintiffs assert that HHS "relied on flawed data and illogical reasoning" to conclude that the 2019 Rule had a negative impact on public health. According to Plaintiffs, HHS improperly assumed that a reduction in Title X participation spelled negative public health consequences. (Doc. 2 at 25). HHS responds that it "extensively detailed the impact that the 2019 Rule had" in "dramatically reduc[ing] access to family planning and preventive health services that are essential for hundreds of thousands of clients, especially for the low-income clients Title X was specifically created to serve." (Doc. 27 at 24) (citing 86 Fed. Reg. at 56,148). The Court agrees with HHS. The NFR reflects that HHS considered comments from providers indicating that patients were

forgoing services or had lost access entirely. *Id.* at 56,150. It further illustrates that HHS thoughtfully considered the effect and sustainability of transfers from Title X programs non-Title X providers. *Id.* at 56,151-52. HHS found that these substitute non-Title X providers could not provide the same scope of services, *id.*, or were not sustainable long term because they were funded by emergency grants or labor-intensive fundraising efforts. *Id.* at 56,152.

Plaintiffs protest that HHS should have disaggregated the effect of transfers on the overall decline in Title X participation. (Doc. 2 at 26). They further complain that HHS should not have relied on a study by a pro-choice organization and questioned the truthfulness of statements by former Title X grantees. *Id.* at 26-27. **But fussing about the scope and reliability of the Department’s data is beyond the scope of arbitrary and capricious review.** The agency need only “examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 43; *see also Saint Mary’s Cement v. EPA*, 782 F.3d 280, 286 (6th Cir. 2015) (“[W]e are at our most deferential when reviewing an agency’s scientific determinations about issues within its expertise.”) (emphasis supplied). HHS has done that.

Plaintiffs contend that HHS failed to weigh the positive effects of the 2019 Rule against its negative effects. (Doc. 2 at 27). Setting aside the probability that 2019 Rule *had no* positive effects, HHS did consider its merits. HHS responded to several of comments that proposed keeping various features of the 2019 Rule. *See, e.g.*, 86 Fed. Reg. 56,161-62 (considering retaining the 2019 Rule’s subrecipient monitoring), 56,168

(addressing comments that some states saw increased Title X participation under the 2019 Rule), 56,176 (discussing one option the department considered to retain much of the 2019 Rule). Nevertheless, HHS “determined that the most appropriate course [was] to revoke the 2019 rule in its totality.” *Id.* at 56,148.

Plaintiffs then argue that HHS failed to consider the negative public health effects of the 2000 Rule. The only example Plaintiffs point to is a report showing that rates of sexually transmitted diseases “reached a record high in 2018.” (Doc. 2 at 27). But apparently Plaintiffs did not read that report very carefully. The report, published in December 2019—eight months after the 2019 Rule went into effect—in fact reports that “in 2019...[t]here were more than 1.8 million cases of chlamydia—the highest number of *annual* cases of any condition ever reported to the CDC.”<sup>15</sup> Nevertheless, the Final Rule *did* consider the availability of STI testing and concluded that the 2019 Rule reduced access to it because of the loss of Title X funding. 86 Fed. Reg 56,151. Furthermore, the NFR concludes that the Final Rule will result in “earlier detection of sexually transmitted infections.” *Id.* at 56,168.

Plaintiffs further argue that HHS “irrationally concluded that the 2019 Rule had permanently decreased the number of patients and grantees participating in Title X.” (Doc. 2 at 28). Plaintiffs suggest that, given time, states like Ohio would have been able to replace the lost grantees and restore Title X to full participation. HHS responds that it did specifically address “the concern that the provision of Title X services would improve

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<sup>15</sup> Association of State and Territorial Health Officials, *National STD Trends: Key Information on Sexually Transmitted Diseases for Public Health Leadership* 1 & n.1 (2019), <https://perma.cc/G58R-WBEW> (emphasis supplied).

after COVID-19, and utilized its expertise to determine that it was ‘unlikely that the number of clients served or services provided would increase to pre-2019 levels or above without a change to the 2019 rule.’” (Doc. 27 at 26) (citing 85 Fed. Reg. at 56,152). HHS was entitled to make this determination, and its reasoning is not arbitrary or capricious.

Finally, Plaintiffs argue that HHS failed to consider that the 2019 Rule may actually have encouraged some new users of Title X services. This argument is frivolous. Though it is possible some consumers were encouraged to seek family planning services knowing their provider would not perform abortions, net is net. And the net change in participation in Title X programs is sharply negative. To the extent any new users sought Title X services *because* of the 2019 Rule, HHS accounted for them when it considered the net change of Title X users. *See, e.g.*, 86 Fed. Reg. at 56,146. HHS is free to pursue a policy that maximizes the number of participants in Title X.

*Third*, Plaintiffs assert that HHS failed to consider reliance interests in rescinding the 2019 Rule. Plaintiffs point to *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, for the proposition that failure to consider reliance interests, even when a recipient has no “substantive rights” to a benefit, renders an agency action arbitrary and capricious. 140 S. Ct. 1891, 1913-14 (2020). But that case relied on the principle that “*longstanding* policies may ... engender[] serious reliance interests that must be taken into account.” *Id.* at 1913 (citing *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 212 (2016)) (emphasis supplied). **The 2019 Rule was in effect for less than two years.** In any event, HHS did expressly state that “no particular private organizations have a right

to Title X funding,” thus HHS considered any reliance interests to be minimal. 86 Fed. Reg. at 56,150. On a motion for preliminary injunction, the Court finds it unlikely that Plaintiffs will successfully argue that failure to consider reliance interests accrued over two years renders the Department’s decision arbitrary and capricious.

*Fourth*, Plaintiffs insist the Final Rule is arbitrary and capricious because it fails to consider whether eliminating the 2019 Rule’s physical and financial separation requirements “would erode public support for the Title X program.” (Doc. 2 at 32). Quoting the Final Rule, HHS responds that it reinstates “compliance standards that had been in effect for nearly the entirety of the Title X program, had been widely accepted by grantees, had enabled the Title X program to operate successfully, and had not resulted in any litigation.” (Doc. 27 at 28) (citing 86 Fed. Reg. at 56,145). The Court agrees that this passage shows HHS did consider public support and concluded that the 2000 Rules’ wide acceptance, lack of litigation, and persistence through three *two*-term presidencies likely demonstrated public support for the Final Rule. Though this Court is well aware that counsel for some of the Plaintiff states remain skeptical of the 2020 presidential election, the objective truth is that a majority of voters rejected the administration responsible for the 2019 Rule. Thus, the Final Rule cites President Biden’s January 28, 2021, “Memorandum on Protecting Women’s Health at Home and Abroad” which “instructed the Department to review the Title X Rule and any other regulations governing the Title X program that impose undue restrictions on the use of Federal funds or women’s access to complete medical information and shall consider, as soon as practicable, whether to suspend, revise, or rescind, or publish for notice and comment



proposed rules suspending, revising, or rescinding, those regulations, consistent with applicable law, including the Administrative Procedure Act.” 86 Fed. Reg. at 56,148. Thus, in promulgating the final rule, HHS announced that it was following the instructions of a very recently elected chief executive. This shows HHS considered public support and reasonably concluded that it favored the Final Rule.

**ii. HHS’s decision to require abortion referrals upon request was not arbitrary or capricious**

Plaintiffs’ last argument on the merits is that the Final Rule arbitrarily and capriciously requires Title X programs to provide referrals for abortion services upon request. Again, Plaintiffs supply four arguments.

*First*, Plaintiffs argue that the Final Rule relies on flawed data that the 2019 Rule had negative public health outcomes. The Court has already rejected this argument and does so again here.

*Second*, Plaintiffs repeat their argument that Final Rule fails to consider how mandatory referrals for abortion services will erode public support for Title X. Again, the Court has rejected this argument. Strong public support was the starting premise for the Final Rule. Indeed, a recently-elected President Biden directed HHS to “review the Title X Rule and any other regulations ... that impose undue restrictions on ... *women’s access to complete medical information....*” 86 Fed. Reg. at 56,148 (emphasis supplied).

*Third*, Plaintiffs argue that HHS failed to show “good reasons for the new policy,” *Encino*, 136 S. Ct. at 2126, which departs from the 2019 Rule’s finding that “in most instances when a referral is provided for abortion, that referral necessarily treats abortion

as a method of family planning.” (Doc. 2 at 33) (quoting 84 Fed. Reg. at 7,717). HHS responds that it did address the departure and provide “good reasons” for it. (Doc. 27 at 29). The Final Rule explains that the 2019 Rule caused “private organizations and states to withdraw from the program, leaving multiple states without any Title X providers and the agency struggling to meet its mandate to provide family planning services for low-income populations in areas of high need.” 85 Fed. Reg. at 56,150. Departing grantees told HHS that the 2019 Rule’s prohibition on non-directive counselling and abortion referral “interfered with the patient-provider relationship and compromised their ability to provide quality healthcare.” *Id.* at 56,146. HHS stated, unequivocally, that the fact “[t]hat so many providers did in fact withdraw from the program is a change in circumstances that, in the Department’s view, demands reconsideration of the 2019 rule.” *Id.* The Court is satisfied that this departure was not arbitrary or capricious. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (“[I]t suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better . . .”). No authority requires HHS to “disprove[]” the agency’s prior interpretation of an ambiguous statute, as Plaintiffs demand. (Doc 2 at 33).

*Fourth*, Plaintiffs argue that HHS “failed to consider whether mandating referrals was consistent with medical ethics.” (Doc. 2 at 34). But Plaintiffs defeat their own argument in the next sentence by acknowledging that HHS “stated that the 2019 Rule’s prohibition on referrals was contrary to the ‘ethical codes of major medical organizations.’” (Doc. 2 at 34) (citing 86 Fed. Reg. at 19,817). HHS considered medical ethics in the Final Rule too. *See* 86 Fed. Reg. at 56,146. Indeed, in the context of

discussion about conscience statutes generally, HHS stated that “objecting individuals and grantees will not be required to counsel or refer for abortion,” and committed to “ensur[ing] appropriate compliance with conscience laws as well as continuity of care.” *Id.* at 56,153. Thus, the Court agrees with HHS that it did consider and address the “important aspect” of medical ethics relating to abortion referrals. *Nat’l Ass’n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 645 (2007) (quoting *State Farm*, 463 U.S. at 43).

Accordingly, the Court cannot say it is likely that Plaintiffs will prevail on their argument that the Final Rule is arbitrary and capricious. Instead, the Court finds the Final Rule is based on a permissible interpretation of Section 1008 and is fully entitled to *Chevron* deference.

## **2. Irreparable Harm**

On a motion for preliminary injunction, “the existence of an irreparable injury is mandatory,” such that “even the strongest showing on the other three factors cannot eliminate the irreparable harm requirement.” *D.T. v. Sumner Cnty. Schs.*, 942 F.3d 324, 326-27 (6th Cir. 2019). An irreparable harm “‘must be both certain and immediate,’ not ‘speculative or theoretical.’” *Id.* Typically, “economic loss does not, in and of itself, constitute irreparable harm.” *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985); *see also Ohio ex rel. Celebrezze v. Nuclear Regulatory Com.*, 812 F.2d 288, 291 (6th Cir. 1987). Where the economic loss is “irrecoverable,” however, it “may constitute irreparable injury” but “a party asserting such a loss is not relieved of its obligation to demonstrate that its harm will be ‘great.’” *N. Air Cargo v. U.S. Postal Serv.*, 756 F.

Supp. 2d 116, 125 n.6 (D.D.C. 2010); *see also, e.g., Allina Health Servs. v. Sebelius*, 756 F. Supp. 2d 61, 67–68 (D.D.C. 2010) (noting that “an inability to recover lost profits or payments does not always constitute irreparable harm” and collecting cases); *CoverDyn v. Moniz*, 68 F. Supp. 3d 34, 49 (D.D.C. 2014) (“Otherwise, a litigant seeking injunctive relief against the government would always satisfy the irreparable injury prong, nullifying that requirement in such cases.”).

Here, Plaintiffs argue that they will be irreparably harmed by increased competition for Title X funds. The Court is not convinced. Of the 12 plaintiff states, only Ohio has submitted a declaration that it will even apply for Title X grants in January. (Doc. 2-1). HHS is correct that, besides Ohio, none of the Plaintiff states have provided evidence that they will face increased competition. Further, the Court declines to hold that an increase in fair competition for public grants can constitute irreparable injury. *Basicomputer Corp v. Scott*, 973 F.2d 507, 512 (6th Cir. 1992) (treating as irreparable the harm caused by “the loss of *fair* competition that results from the breach of a non-competition covenant”) (emphasis supplied). However, even if Plaintiffs receive less grant funding as a result of the Final Rule, it is hard to see how the injury would be substantial. Plaintiffs concede that they have no “legally cognizable interest” in the grant funding. (Doc. 46 at 14). “To demonstrate irreparable injury, a plaintiff must show that it will suffer harm that is ‘more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff.’” *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008). Plaintiffs’ potential harm is also highly speculative. Ohio has not submitted any evidence that the number of Title X applicants it will have to

compete against has increased. Moreover, Plaintiffs like Ohio that have been able to expand services since 2019 are likely better positioned to compete for Title X funds. Nor is it clear that any reduction in Ohio's Title X grants would be strictly irrecoverable. If Plaintiffs prevail and the 2019 Rules are reinstated, Title X grantees are likely to leave the program and relinquish their funds just as they did in 2019. Under those circumstances, HHS has already demonstrated its willingness to redistribute relinquished funds to grantees, like Ohio, who stay in the program.

Finally, "an unexcused delay in seeking extraordinary injunctive relief may be grounds for denial because such delay implies a lack of urgency and irreparable harm." *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 244 (D.D.C. 2014). **Here, HHS seeks to implement a rule that was, effectively, in place for 20 years before 2019. All of Plaintiffs arguments apply equally to the 2000 Rule as to the Final Rule, yet Plaintiffs never sought relief from the 2000 Rule.** To the Court, this fact suggests that Plaintiffs' fears of irreparable injury are not genuine.

Accordingly, Plaintiffs have not shown by clear and convincing evidence that they will be irreparably injured by the Final Rule. *Honeywell, Inc. v. Brewer-Garrett Co.*, 145 F.3d 1331 (6th Cir.1998).

### **3. Balance of the Equities**

Finally, though it is hardly necessary, the Court concludes that the balance of equities strongly disfavors a preliminary injunction. Plaintiffs argue that "there is simply no evidence that the American public or abortion providers will be substantially harmed by a preservation of the *status quo*." (Doc. 2 at 38). That is blind.



The 2019 Rule harms our most vulnerable members of society daily. Title X once provided comprehensive family planning services to more than 5 million patients annually, including low-income families in all 50 states. But in 2019, that number dropped to 3.1 million, with no Title X services available in six states and drastically reduced services in several others. This decline overwhelmingly affected the program's low-income users. According to the Final Rule, after 2019, "573,650 fewer clients under 100 percent of the federal poverty level (FPL); 139,801 fewer clients between 101 percent FPL to 150 percent FPL; 65,735 fewer clients between 151 percent FPL and 200 percent FPL; and 30,194 fewer clients between 201 percent FPL to 250 percent FPL received Title X services." 86 Fed. Reg. 56,146. **Weighed against the interests of the Plaintiff states, restoring access to vital family planning services for millions of Americans is a far greater priority.**

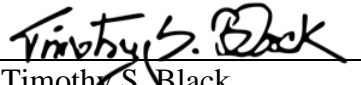
Plaintiffs' final argument is that "the public interest is always served by a correct application of the law." This Court agrees.

#### **IV. CONCLUSION**

The Court finds that Plaintiffs have not met their burden of establishing entitlement to a preliminary injunction. Accordingly, Plaintiffs' motion to enjoin the Department of Health and Human Services from implementing or enforcing the Final Rule, *Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services*, 86 Fed. Reg. 56144-01 (Oct. 7, 2021) (to be codified at 42 C.F.R. pt. 59) is **DENIED**.

**IT IS SO ORDERED.**

Date: 12/29/2021

  
Timothy S. Black  
United States District Judge

**Document:****Tenn. Code Ann. § 39-15-213**[< Previous](#)[Next >](#)**Tenn. Code Ann. § 39-15-213****Copy Citation**

Current through the 2022 Regular Session.

[TN - Tennessee Code Annotated](#)   [Title 39 Criminal Offenses](#)   [Chapter 15 Offenses Against the Family](#)   [Part 2 Abortion](#)

**39-15-213. Criminal abortion — Affirmative defense.****(a)** As used in this section:

- (1)** "Abortion" means the use of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a woman known to be pregnant with intent other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus;
- (2)** "Fertilization" means that point in time when a male human sperm penetrates the zona pellucida of a female human ovum;
- (3)** "Pregnant" means the human female reproductive condition of having a living unborn child within her body throughout the entire embryonic and fetal stages of the unborn child from fertilization until birth; and
- (4)** "Unborn child" means an individual living member of the species, homo sapiens, throughout the entire embryonic and fetal stages of the unborn child from fertilization until birth.

**(b)** A person who performs or attempts to perform an abortion commits the offense of criminal abortion. Criminal abortion is a Class C felony.

**(c)** It is an affirmative defense to prosecution under subsection (b), which must be proven by a preponderance of the evidence, that:

- (1)** The abortion was performed or attempted by a licensed physician;
- (2)** The physician determined, in the physician's good faith medical judgment, based upon the facts known to the physician at the time, that the abortion was necessary to prevent the death of the pregnant woman or to prevent serious risk of substantial and irreversible impairment of a major bodily function of the pregnant woman. No abortion shall be deemed authorized under this subdivision (c)(2) if performed on the basis of a claim or a diagnosis that the woman will engage in conduct that would result in her death or substantial and irreversible impairment of a major bodily function or for any reason relating to her mental health; and
- (3)** The physician performs or attempts to perform the abortion in the manner which, in the physician's good faith medical judgment, based upon the facts known to the physician at the time, provides the best opportunity for the unborn child to survive, unless in the physician's good faith medical judgment, termination of the pregnancy in that manner would pose a greater risk of the death of the pregnant woman or substantial and irreversible impairment of a major bodily function. No such greater risk shall be deemed to exist if it is based on a claim or diagnosis that the woman will engage in conduct that would result in her death or substantial and irreversible impairment of a major bodily function or for any reason relating to her mental health.

(d) Medical treatment provided to the pregnant woman by a licensed physician which results in the accidental death of or unintentional injury to or death of the unborn child shall not be a violation of this section.

(e) This section does not subject the pregnant woman upon whom an abortion is performed or attempted to criminal conviction or penalty.

## History

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Acts 2019, ch. 351, § 2.

### ▼ Annotations

### Notes

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#### **Cross References.**

Penalty for Class C felony, § 40-35-111.

TENNESSEE CODE ANNOTATED

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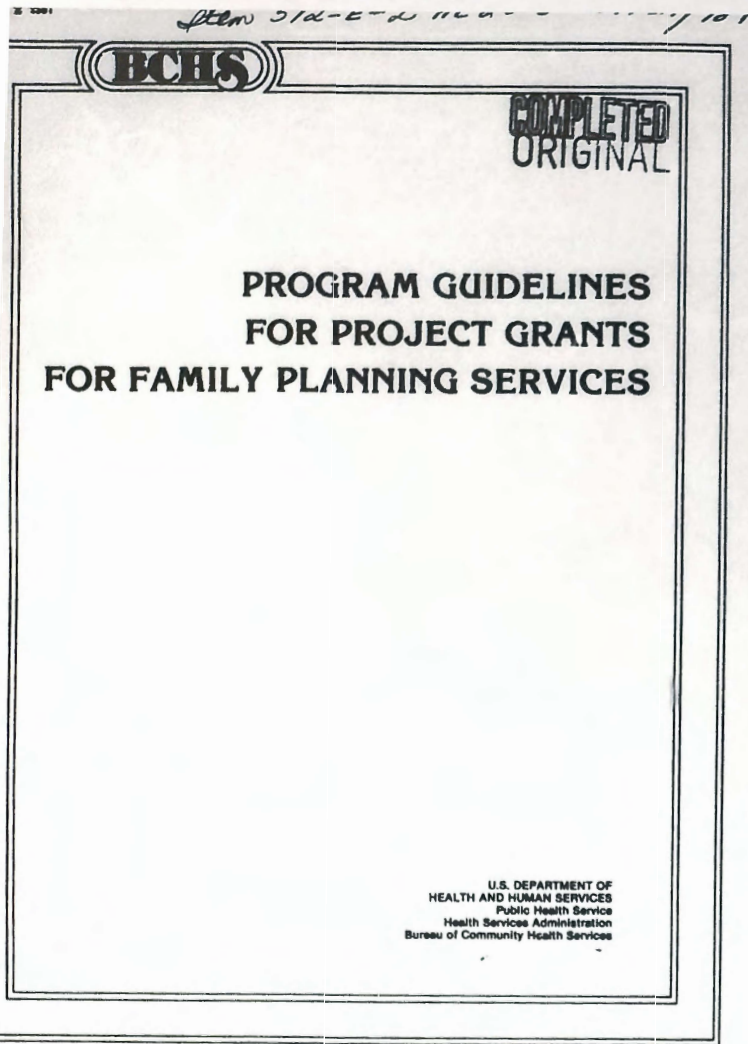


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abortion, and other social services. Grantees should maintain a list of health care providers, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs [59.5(b)(2)] to use for referral purposes. Projects must select referral providers according to procedures which assure fairness in the referral practice and which identify providers of acceptable quality. Whenever possible, clients should be given a choice of providers from which to select.

Projects should have written referral and follow-up procedures. The timing and manner of referral and follow-up depend upon the nature of the problem for which the referral was made. For example:

- *Emergency referrals (e.g., possible ectopic pregnancy) should be made immediately with the provider.*
- *Urgent referrals (e.g., solitary breast nodule) should be followed up within two weeks with the client.*
- *Essential referrals (e.g., hypertension) should be followed up with the client, the timing to depend on professional judgment.*
- *Discretionary referrals (made at the request of the client) should be followed up with the client at the next clinic visit. Further follow-up may not be necessary but should be based on professional judgment.*

Projects should make arrangements for the transfer (with client consent) of pertinent client information to the referral provider. In addition, internal systems should be developed to document (1) that recommended referral appointments are made within an appropriate period of time, (2) that these appointments are kept, (3) that providers return complete pertinent client information to the referring center, (4) action taken in response to recommendations received from the referral provider, and (5) any comments the client makes about the referral provider. Efforts may be made to aid the client in identifying potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

When family planning services are provided by the project to clients referred from other agencies, the project has a responsibility to share client information with the referring agency. Such information may only be given with the written permission of the client.

When family planning clients are referred for services, projects have a responsibility to assure that clients obtain the appropriate services, and referred clients should be contacted

to assure that the services are obtained. However, follow-up of family planning clients must be sensitive to the client's concerns for confidentiality and privacy. Therefore, mechanisms for follow-up must be negotiated with the client on the first visit, and the negotiated method of follow-up should be noted on the follow-up card and the client's medical record.

**8.0 Required Services**

The services contained in this section must be provided by all projects funded under Title X.

**8.1 CLIENT EDUCATION**

Education services should provide clients with the information they need to make informed decisions about family planning, to use specific methods of contraception, and to understand the procedures involved in the family planning clinic visit. On an initial visit clients should be offered information about basic female and male reproductive anatomy and physiology and the value of fertility regulation in maintaining individual and family health. The range of available services and the purpose and sequence of clinic procedures should also be explained. Clients must be given information about all contraceptive methods in order to make an informed choice. This instruction should be documented in the client record. Additional education, particularly at subsequent visits, should include information on reproductive health and health promotion/disease prevention, as appropriate.

The project's education component should include written goals, content outlines and procedures, and an evaluation strategy. The educational approach used should be appropriate to the patient's age, situation, and previously acquired information on the various methods. Providers of education should have a mechanism to determine that information given has been understood.

- **Informed Consent**  
For ethical, medical, and legal reasons, an informed consent documenting the client's voluntary consent to receive the project's services must be signed by the client prior to his or her receiving any medical services. The form should be written in the primary language of the client or witnessed by an interpreter. It should cover all procedures and medications to be provided. To give informed consent for contraception, the client must receive education on the benefits and risks of the various contraceptive alternatives and details on the safety, effectiveness, potential side effects, complications, and danger signs of the contraceptive method(s) of choice. Forms for each contraceptive method, including sterilization, should be part of the project's service plan.

All forms should contain a statement that the client has been counseled, has read the appropriate informational material, and has understood the content of both. The signed informed consent should be part of the client's record. It should be renewed and updated when there is a major change in the client's health status or a change to a different prescriptive contraceptive method. When sterilization services are provided or arranged for with Government funding, Federal sterilization consent guidelines must be followed (see Attachment C).

**8.2 COUNSELING**

The primary purpose of counseling in the family planning setting is to assist clients in reaching an informed decision regarding the choice and continued use of family planning methods and services. The counseling process is designed to help clients resolve uncertainty, ambivalence, and anxiety in relation to reproductive health and to enhance their capacity to arrive at a decision that reflects their considered self-interest.

The counseling process involves mutual sharing of information. Persons who provide counseling should be knowledgeable, objective, non-judgmental, sensitive to the rights and differences of clients as individuals, and able to create an environment in which the client feels comfortable discussing personal information. The counselor's knowledge should be sufficient to provide ample information regarding the risks, benefits, contraindications, and effective use of any method, procedure, treatment, or option being considered by the client. Documentation of counseling must be included in the client's record.

- **Method Counseling**  
Post-examination counseling should be provided to assure that the client knows results of the history, physical examination, and laboratory studies that may have a bearing on the choice of method(s); knows how to use and is comfortable with the contraceptive method selected and prescribed; knows the common side effects and possible complications of the method selected and what to do in case they occur; knows the planned return schedule and has a next appointment at an appropriate interval; knows an emergency 24-hour telephone number and a location where emergency services can be obtained; and receives appropriate referral for additional services as needed.
- **Special Counseling**  
Clients should receive special counseling regarding future planned pregnancies, management of a current pregnancy, sterilization, and other individual problems (e.g., genetic, nutritional, sexual) as indicated.

**8.3 HISTORY, PHYSICAL ASSESSMENT, AND LABORATORY TESTING**

- **History**  
A comprehensive personal history and pertinent history of immediate family members must be obtained on all female clients. This should be done at the initial medical visit. The history should be updated at subsequent visits. Histories are recommended for all male clients and are required for those requesting medical services. The initial history should address the following areas:  
—Allergies; immunizations, especially rubella; current use of prescription and over-the-counter medications; significant illnesses; hospitalizations; surgery; review of systems; extent of use of tobacco, alcohol, and drugs.  
Histories of reproductive function in female patients should include:  
—Menstrual history; sexual activity; sexually transmitted diseases; contraceptive use; pregnancies; in utero exposure to DES.  
On medical revisits, oral contraceptive users must be asked about symptoms of embolic disease and other major complications and side effects. IUD users must be asked, in particular, about symptoms of pelvic infection.  
The male reproductive history should include:  
—Sexual activity; sexually transmitted diseases; fertility; in utero exposure to DES.
- **Physical Assessment**  
Female clients requesting prescriptive methods of contraception (e.g., oral contraceptives, IUDs, diaphragms) must have a general physical examination at the initial medical visit. The initial examination should include at least the following:  
—Height; weight; blood pressure; thyroid; heart; lungs; extremities; breasts, including instruction in self-exam; abdomen; pelvic examination, including visualization of the cervix and bimanual exam; rectal exam, as indicated.  
For oral contraceptive users, initial and annual physical examinations must include evaluation of weight, blood pressure, extremities, breasts, and pelvic organs. For IUD users, initial and annual physical exam, blood pressure, and pelvic exam are required, and a more complete exam is recommended.  
Female clients using nonprescriptive methods or diaphragms should have a general physical examination at least every two years. This exam is particularly important for clients who are not receiving general health care elsewhere.



Male clients requesting temporary methods of contraception are not required to undergo physical examination, but should be offered this service, to include:

—Height; weight; blood pressure; thyroid; heart; lungs; abdomen; examination of the genitals and rectum, including palpation of the prostate and instruction in self-exam of the testes.

#### Laboratory Testing

The following laboratory procedures should be done on-site for all female clients at the initial visit and must be done for those receiving prescription methods. They may be waived if written results of these tests done within six months at another facility are available.

—Hemoglobin (Hgb) or hematocrit (Hct)

—Pap smear

—Gonorrhea culture for clients requesting IUD insertion

In addition, pregnancy testing and gonorrhea screening must be available and provided upon request.

Initial laboratory procedures should be repeated annually or as indicated. Oral contraceptive users must have annual pap smears, and IUD users must have annual hemoglobins or hematocrits and pap smears.

Gram stains and cultures for gonorrhea, and other laboratory tests as indicated, should be available for male clients.

Every effort should be made to assure that laboratory tests performed by or for the clinic are of high quality. This means that the grantee should assess the credentials of laboratories with which it contracts. If laboratory testing is performed on-site, written protocols for quality control and proficiency testing are necessary.

#### Notification of Abnormal Lab Results

A procedure must be established to allow for client notification and adequate follow-up or significantly abnormal laboratory results. This procedure must respect the client's request to maintain confidentiality. When initial contact is not successful, a reasonable further effort should be made, consistent with the severity of the abnormality.

#### Other Laboratory Services or Procedures

The following procedures and lab tests should be provided by the project when medically indicated:

—Screening for non-gonococcal sexually transmitted diseases, e.g., syphilis

—Microscopic examination of vaginal smears and wet mounts for diagnosis of vaginitis

—Microscopic examination and/or culture and sensitivity of urine

—Selected laboratory tests, e.g., blood sugar or cholesterol test for women who

are potentially at high risk for oral contraceptive use

—Hemagglutination test for rubella

Other procedures and lab tests may be indicated for some clients and may be provided on-site or by referral.

#### • Revisits

Revisit schedules should be individualized, based upon the client's need for education, counseling, and medical care beyond that provided at the initial visit. Younger clients and clients initiating a new contraceptive method may need special opportunities for reassurance and clarification. On the other hand, projects should avoid antagonizing well-informed clients who are comfortable with the method being used; such clients should not be required to return for unwanted counseling or frequent supply visits.

Clients selecting oral contraceptives, IUDs, or diaphragms should be scheduled for a revisit within three months after initiation of the method to reinforce its proper use, to check for possible side effects, and to provide additional information as needed. A new client who chooses to continue a method in use upon entry to the program need not return for this early revisit unless a need for reevaluation is determined on the basis of the findings at the initial visit.

Annual revisits are mandatory for clients using oral contraceptives or intrauterine devices and must include at a minimum the components of the history, physical examination, and laboratory procedures as specified for such clients. Annual history updates, exams, and laboratory tests are recommended for all clients. The frequency with which specific procedures are to be routinely repeated should be determined by the medical director and documented in the health care plan.

#### 8.4 FERTILITY REGULATION

Projects must make available, either directly or through referral, all of the DHHS approved methods of contraception. For recommendations on the management of each method, see Related Documents—Fertility Regulation.

#### • Temporary Contraception

Currently, the temporary methods of contraception include barrier methods (female and male), IUDs, fertility awareness methods including natural family planning, and hormonal contraceptives. More than one method of contraception can be used simultaneously by a client and should be offered if the client requests it, e.g., the use of two barrier methods, the use of a

barrier method with an IUD, or the combination of a barrier method with techniques of ovulation detection. Current FDA guidelines as to relative and absolute contraindications, e.g., package inserts, should be followed.

#### • Permanent Contraception

Projects must ascertain that the counseling and consent process assures voluntarism and full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal regulations must be met if the sterilization procedure is performed or arranged for by the project (see Attachment C). For further guidance, see also Appendices—Permanent Contraception.

#### • Emergency Contraception

Projects must comply with FDA recommendations for the administration of drugs or devices for postcoital contraception.

The use of diethylstilbestrol (DES) within 72 hours of unprotected sexual intercourse around the time of presumed ovulation has been found to be highly effective in preventing pregnancy. However, this drug has been implicated in the development of reproductive abnormalities and fertility-related risks in the offspring of women who took DES during pregnancy. Although the doses and duration of DES use for postcoital contraception are less than those commonly used when DES was prescribed for pregnancy complications, health risks may be similar. It also is possible that women may take the drug as a postcoital contraceptive when already pregnant from a previous intercourse. In such cases, the potential offspring of such pregnancies would be exposed to the risks previously described. In light of these considerations, the following recommendations are made:

—Postcoital contraception with DES in any woman should be restricted to situations where no alternative is judged acceptable by a fully informed patient and her physician.

—Thorough birth control counseling should accompany or follow any prescription of DES for postcoital purposes. A principal objective of such counseling should be to discourage women from considering it as a routine method of contraception.

#### 8.5 INFERTILITY SERVICES

Grantees are required by law to make basic infertility services available to clients desiring such services. Infertility services which may be supported by Federal funds are categorized as follows:

—Level I Includes initial infertility interview,

education, examination, appropriate laboratory testing (hemoglobin or hematocrit, pap smear, and culture for gonorrhea), counseling, and appropriate referral.

—Level II Includes semen analysis, assessment of ovulatory function through basal body temperature and/or endometrial biopsy, and postcoital testing.

—Level III More sophisticated and complex than Level I and Level II services.

Grantees must provide Level I infertility services as a minimum. Those with infertility programs supervised by physicians with special training in infertility can offer Level II services. However, when considering the scope of the infertility services to be offered to clients, grantees must be aware that such services are expensive, not necessarily successful, and may be high risk from medical and legal points of view. It is therefore important that the proportion of the grantee's budget which is to be used for infertility services be determined very carefully.

The grantee's health care plan must have an infertility service component that identifies those services to be provided by each delegate at individual service sites or by referral. The infertility plan must address how services will be provided, including the criteria for diagnosis of infertility, the scope of services, identification of referral sites, follow-up, fee schedules, and payment mechanisms. When referring for Level II or Level III infertility services, efforts should be made to help the client identify sources of funding for these services.

Since infertility may be due to male factors, female factors, or a combination of the two, both partners need to be involved in the infertility evaluation. Adequate education should be provided so that clients understand human reproduction and sexuality as it relates to their particular problem. The benefits and risks of proposed diagnostic and therapeutic measures to be provided on-site must be clearly explained and informed consent obtained.

For further guidance, see Appendices—Infertility Services.

#### 8.6 PREGNANCY DIAGNOSIS AND COUNSELING

Grantees must provide pregnancy diagnosis and counseling to all clients in need of this service. Pregnancy testing is one of the most frequent reasons for an initial visit to the family planning facility, particularly by adolescents. It is therefore important to use this occasion as an entry point for providing education and counseling about family planning.

Pregnancy cannot be accurately diagnosed



and staged through laboratory testing alone. Pregnancy diagnosis consists of a history, pregnancy test, and physical assessment, including pelvic examination. Projects providing pregnancy testing on-site should have available at least one test of high specificity and one of high sensitivity. If the medical examination cannot be performed in conjunction with laboratory testing, the client must be counseled as to the importance of receiving a physical assessment as soon as possible, preferably within 15 days. This can be done on-site, by a provider selected by the client, or by a provider to which the client has been referred by the project. For those clients with positive pregnancy test results who elect to continue the pregnancy, the examination may be deferred, but should be performed within 30 days. For clients with a negative pregnancy diagnosis, the cause of delayed menses should be investigated. If ectopic pregnancy is suspected, the client must be referred for immediate diagnosis and therapy.

Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an unintended pregnancy are to be given non-directive counseling on the following alternative courses of action, and referral upon request:

- Prenatal care and delivery
- Infant care, foster care, or adoption
- Pregnancy termination

Clients planning to carry their pregnancies to term should be given information about good health practices during early pregnancy, especially those which serve to protect the fetus during the first three months (e.g., good nutrition, avoidance of smoking, drugs, and exposure to x-rays) and referral for prenatal care.

Clients who are found not to be pregnant should be given information about the availability of contraceptive and infertility services.

For further information, contact the National Clearinghouse for Family Planning Information, as listed in Attachment D.

#### 8.7 ADOLESCENT SERVICES

Adolescent clients require skilled counseling and detailed information. Appointments should be available to them for counseling and medical services on short notice.

It is important not to assume that adolescents are sexually active simply because they have come for family planning services. Many teenagers are seeking assistance in reaching this decision. Abstinence is a valid and responsible option and should be discussed. Adolescents must be assured that the sessions are confidential and that any necessary follow-

up will assure the privacy of the individual. However, counselors should encourage young clients to discuss their needs with parents or other family members.

Adolescents seeking contraceptive services should be informed about all methods of contraception. As their needs frequently change, counseling should prepare them to use a variety of methods effectively. In addition, teenagers and their partners should be encouraged to participate fully in project medical services, including physical examination and laboratory studies. However, as some teenagers may fear the medical procedures usually performed at the first clinic visit, projects may defer them for those teenagers who request deferral and elect nonprescription methods.

Because there is a high incidence of sexually transmitted diseases (STD) among teenagers, it is appropriate to ask them about symptoms or possible exposure to these infections. Teens at particularly high risk of STD should be urged to undergo examination and treatment as indicated, either directly or by referral.

For further recommendations, see Appendices—Adolescent Services.

#### 8.8 SEXUALLY TRANSMITTED DISEASES (STD)

Projects must provide an initial gonorrhea culture for women requesting IUD insertion. Gonorrhea cultures should also be provided for clients with probable or definite exposure to gonorrhea and those with symptoms and signs suggesting gonococcal infection. Projects must comply with State and local STD reporting requirements.

Treatment of a client and partner(s) for gonorrhea should be provided through the project. When treatment is provided on-site, appropriate follow-up measures must be undertaken to ensure cure of all persons treated. If parenteral antibiotics are administered, personnel capable of handling an anaphylactic reaction must be in attendance, and appropriate resuscitation drugs and equipment must be available.

For further information, see Appendices—Sexually Transmitted Diseases.

#### 8.9 IDENTIFICATION OF ESTROGEN-EXPOSED OFFSPRING

The daughters and sons of women who received DES or similar hormones during pregnancy may have abnormalities of their reproductive systems or other fertility-related risks. As part of the history, clients born between 1940 and 1970 should be asked to find out whether or not their mothers took estrogens during pregnancy. Clients prenatally exposed to estrogens should receive special screening

either on-site or by referral. Female clients should be made aware that they are at risk for developing a rare cervico-vaginal tumor and for a number of complications of pregnancy. Male clients should be made aware that they are at risk of certain lesions of the genital tract and for decreased fertility.

For further recommendations, see Appendices—Estrogen-Exposed Offspring.

#### 9.0 Recommended Services

Since the services contained in this section are important to reproductive health care, it is recommended that they be provided at individual service sites.

##### 9.1 GONORRHEA SCREENING

In community or client populations with a high incidence of gonorrhea, endocervical cultures for gonorrhea should be performed on each female client at the time of the initial pelvic examination and repeated as indicated. A yield of equal to or greater than 4 percent positive cultures merits universal screening.

For additional guidance, see Appendices—Sexually Transmitted Diseases.

##### 9.2 MINOR GYNECOLOGIC PROBLEMS

Family planning programs should provide for the diagnosis and treatment of minor gynecologic problems so as to avoid fragmentation or lack of medical care for clients with these conditions. Problems such as vaginitis or urinary tract infection may be amenable to on-the-spot diagnosis and treatment, following microscopic examination of vaginal secretions or urine.

##### 9.3 GENETIC SCREENING AND REFERRAL

For clients at risk for transmission of genetic abnormalities, some basic effort to define this risk is a logical component of family planning services. Initial genetic screening and referral services should be offered to clients who are in need of such services.

Initial screening consists of a careful family history of the client and the client's partner. More complete genetic screening and counseling may be offered directly by a genetic counselor who functions in association with a clinical genetics team capable of providing comprehensive services for a broad range of genetic disorders or indirectly (through referral to a comprehensive genetic service program or programs which may be federally, State, or privately funded). In either case, linkages with a comprehensive genetic service program should be established, specifically with clinical genetic services centers.

Where feasible, in-service training in genetics should be arranged for project staff to enable

them to provide simple genetic screening. Training may be appropriately provided by a genetic service program to which the project is linked. The purpose of training is to familiarize staff with the indications for genetic services, referral mechanisms, and resources. Literature and informational materials regarding the availability of genetic services, including but not limited to prenatal diagnosis, should be available in the appropriate language to all clients on request.

When genetic screening services are offered by a project, they must (1) be supported by a program of public information and education which is sensitive to the concerns of local ethnic and religious groups and upholds the dignity of individuals with congenital physical or mental limitations; (2) include education and counseling to all clients on a voluntary basis, and (3) include referral for testing or further screening if indicated.

For additional guidance, see Appendices—Genetic Screening.

##### 9.4 HEALTH PROMOTION/DISEASE PREVENTION

For many clients, family planning programs are their only continuing source of health information and medical care. Therefore, while most of the client services will necessarily relate to fertility regulation, family planning programs should, whenever possible, provide health maintenance services such as screening, immunization, and general health education and counseling directed toward health promotion and disease prevention. These additional services should promote the clients' general state of health and, in turn, the health of their infants and children. Programs are therefore encouraged to assess the health problems prevalent among the populations they serve and to develop services to address them.

Nutrition services are an example of an important activity directed toward promoting health and preventing disease which can be integrated into the existing family planning services. Projects should provide nutritional problem identification, basic nutrition information, screening, and medical care to clients at high risk of nutrition problems or those requiring nutritional management of disease. These services can be provided without the resources of a full-time nutritionist. Project staff can deliver such services with nutrition training and consultation with a qualified nutritionist.

For further information, see Appendices—Health Promotion/Disease Prevention.

#### 10.0 Related Services

There are some reproduction-related health services that projects may offer if skilled personnel and

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 59**

**RIN: 0940-AA00**

**Standards of Compliance for Abortion-Related Services in Family Planning Services Projects**

**AGENCY:** Office of Population Affairs, OPHS, DHHS  
**ACTION:** Final rules.

**SUMMARY:** The rules issued below revise the regulations that apply to grantees under the federal family planning program by readopting the regulations, with one revision, that applied to the program prior to February 2, 1988. Several technical changes to the regulation are also made to remove and/or update obsolete regulatory references. The effect of the revisions made by the rules below is to revoke the compliance standards, promulgated in 1988 and popularly known as the "Gag Rule," that restricted family planning grantees from providing abortion-related information in their grant-funded projects.

**DATES:** These rules are effective July 3, 2000.

**FOR FURTHER INFORMATION CONTACT:** Samuel S. Taylor, Office of Population Affairs, (301) 594-4001.

**SUPPLEMENTARY INFORMATION:** The Secretary of Health and Human Services issues below regulations establishing requirements for recipients of family planning services grants under section 1001 of the Public Health Service Act, 42 U.S.C. 300. The rules below adopt, with minor technical amendments and one substantive modification, the regulations proposed for public comment on February 5, 1993, at 58 FR 7464. They accordingly revoke the compliance standards, known as the "Gag Rule," promulgated on February 2, 1988.

By notice published elsewhere in this issue of the **Federal Register**, the Department is separately acting to reinstitute, with minor changes, the interpretations of the statute relating to the provision of abortion-related information and services that applied to grantees prior to the issuance of the Gag Rule. The Secretary had previously proposed reinstituting these interpretations in the notice of February 5, 1993 and requested public comment on this proposed action; the public comment period was subsequently reopened by notice of June 23, 1993, 58 FR 34024.

**I. Background**

In 1988, the Secretary of Health and Human Services issued rules, widely known as the "Gag Rule," which substantially revised the longstanding policies and interpretations defining what abortion-related activities were permissible under Title X's statutory limitation on abortion services. That statutory limitation, section 1008 (42 U.S.C. 300a-6), provides that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family

planning." The rules issued on February 2, 1988 (53 FR 2922) set out detailed requirements that (1) Prohibited the provision to Title X clients of nondirective counseling on all pregnancy options and referral to abortion providers, (2) required physical and financial separation of abortion-related activities from Title X project activities, and (3) prohibited Title X projects from engaging in activities that encourage, promote, or advocate abortion. These requirements are presently codified principally at 42 CFR 59.7-59.10.

The February 2, 1988 "Gag Rule" was extremely controversial: The proposed rules generated approximately 75,000 public comments, many of which were negative. 53 FR 2922. The rules were subsequently challenged in several district courts by a variety of providers, provider organizations, and others. Although the requirements embodied in the Gag Rule were upheld by the Supreme Court in 1991 as a permissible construction of section 1008, the rules continued to be a source of controversy, with the provider and medical communities litigating after 1991 to prevent enforcement of the rules. Following his inauguration in 1993, President Clinton ordered the Secretary to suspend the rules and initiate a new rulemaking:

The Gag Rule endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients. Furthermore, the Gag Rule contravenes the clear intent of a majority of the members of both the United States Senate and House of Representatives, which twice passed legislation to block the Gag Rule's enforcement but failed to override Presidential vetoes.

For these reasons, you have informed me that you will suspend the Gag Rule pending the promulgation of new regulations in accordance with the "notice and comment" procedures of the Administrative Procedure Act. I hereby direct you to take that action as soon as possible. I further direct that,

within 30 days, you publish in the **Federal Register** new proposed regulations for public comment.

Presidential Memorandum of January 22, 1993, published at 58 FR 7455 (February 5, 1993). The Secretary subsequently suspended the 1988 rules on February 5, 1993 (58 FR 7462) and issued proposed rules for public comment (58 FR 7464).

The notice of proposed rulemaking proposed to revise the program regulations by readopting the program regulations as they existed prior to the adoption of the Gag Rule, which would have the effect of revoking the Gag Rule. It also proposed that the policies and interpretations in effect prior to the issuance of the Gag Rule be reinstated, both in substance and in form. As noted in the proposed rules, these policies and interpretations, which had been in effect for a considerable time prior to 1988, were set out largely, "in the 1981 Family Planning Guidelines and in individual policy interpretations." 58 FR 7464. The pre-1988 interpretations had been developed during the 1970's and early 1980's in response to questions arising out of the Department's initial interpretation that section 1008 not only prohibited Title X projects from performing or providing abortions, but also prohibited actions by Title X projects that "promoted or encouraged" abortion as a method of family planning. Over time, questions were raised, and answered in a series of legal opinions, as to whether particular actions would violate the statute by promoting or encouraging abortion as a method of family planning. As summarized in the proposed rules, the answers that were developed were generally as follows:

Title X projects [are] required, in the event of an unplanned pregnancy and where the patient requests such action, to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects. However, consistent with the long-standing Departmental interpretation of the statute, Title X projects [are] not \*\*\* permitted to promote or encourage abortion as a method of family planning, such as by engaging in pro-choice litigation or lobbying activities. Title X projects [are] also \*\*\* required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities that promote or encourage abortion as a method of family planning.

*Id.* By notice dated June 23, 1993 (58 FR 34024), the Secretary made available for public comment a detailed exposition of the prior policies and interpretations.

In the public comment periods, the Secretary received 146 comments,



virtually all of which concerned the proposed policies and interpretations rather than the proposed regulations themselves. Approximately one-third of these opposed the proposed policies and interpretations on various grounds; most of these comments were from individuals who, in general, were opposed to any change to the Gag Rule. The remainder of the public comments, most of which were from providers and other health organizations, generally supported the reinstatement of the prior policies and interpretations, although a number of these comments suggested that they be modified in various respects. The public comments and the Secretary's response thereto are summarized below.

## II. Public Comment and Departmental Response

The public comment generally focused on a few issues raised by the rulemaking. As noted above, these comments generally pertained to the proposed policies and interpretations rather than to the proposed regulatory language itself. Accordingly, the comments on the issues raised in the rulemaking are summarized below, and the Secretary's response thereto is provided.

### *A. Lack of a Rational Basis To Revoke the Gag Rule; Necessity for Continuation of the Gag Rule*

Most of the comments in opposition to the proposed rules came from individuals, and most objected to the proposed revocation of the Gag Rule on the ground that abortion is wrong or that tax dollars should not be used to provide abortion services of any kind. Several comments also objected that the Secretary had not rational basis for revoking the Gag Rule, as it had never gone into operation. For example, a comment signed by fifteen members of Congress argued that—

HHS intends to discard the February 2, 1988 regulations in their entirety \*\*\* regardless of whether any particular portion was the subject of court challenge or legislative action. \*\*\* We believe the rejection of the 1988 rule is precipitous and that each portion of the 1988 regulations must be reviewed on its merits and justification provided in any final regulations as to why the 1988 clarifications were or were not maintained in a new rule.

With respect to the comments objecting to the revocation of the Gag Rule or the use of tax dollars for abortion on moral grounds, the Secretary notes that, under the interpretations adopted in conjunction with the regulations below, the funding of abortion or activities that promote or

encourage abortion with Title X funds has been and will continue to be prohibited. Rather, what changes under the interpretations reinstated in conjunction with the regulations below is which activities are considered to "promote or encourage" abortion. In contrast to the position taken under the Gag Rule, under the present view (which was also the Department's view of the statute prior to 1988), the provision of neutral and factual information about abortion is not considered to promote or encourage abortion as a method of family planning. Indeed, the rule itself, now requires the provision to pregnant women, on request, of neutral, factual information and non-directive counseling on each of three options. The basic statutory interpretation underlying both the Gag Rule and the specific policies that governed the Title X program prior to 1988—that section 1008 prohibits activities that promote or encourage abortion as a method of family planning—remains unchanged.

With respect to the contentions that the Secretary lacks a rational basis for revoking the Gag Rule and that she must justify each separate part of the Gag Rule being discarded, we do not agree. The pre-1988 interpretation of the statute represents a permissible exercise of administrative discretion. The crucial difference between this approach and the Gag Rule is one of experience. Because of ongoing litigation, the Gag Rule was never implemented on a nationwide basis, so that its proponents can point to no evidence that it can and will work operationally on a national basis in the Title X program. The policies reflected in, and interpretations reinstituted in conjunction with, the regulations below, on the other hand, have been used by the program for virtually its entire history; indeed, they have been in effect during the pendency of this rulemaking. Both the program managers and the Title X grantee community are well-versed in these policies and interpretations, and the grantees have in the past generally been able to operate in compliance with them. Further, as evidenced by the public comment received, the reinstituted policies and interpretations are generally acceptable to the grantee community, in contrast to the compliance standards in the Gag Rule, which were generally unacceptable to the grantee community. This factor likewise favors their adoption, as it suggests a far greater likelihood of voluntary compliance by grantees. Finally, the suggestion that the Gag Rule provisions should be accepted or

rejected separately is rejected as unsound. The provisions of the Gag Rule were an interrelated set of requirements that depended on several underlying assumptions about how the Title X program should work; moreover, they depended in part on several definitions that applied to all the major provisions of the Gag Rule. *See*, in this regard, 53 FR 2923, 2925; *see also*, the discussion of definitions at 53 FR 2926–2927.

### *B. Failure To Comply With the Administrative Procedure Act; Vagueness of Standards*

A number of comments, from both proponents of and opponents to the proposed rules, objected to the failure to publish the actual policies and interpretations as part of the proposed rule on the ground that this violated the public comment requirements of the Administrative Procedure Act (APA); several comments argued that it was impossible to comment on policies that had never been published. A related criticism was that several of the interpretations described in the preamble to the notice of proposed rulemaking, particularly the interpretation relating to physical separation, were too vague.

The Secretary agreed that the provision of further information on the specific details of the pre-1988 policies and interpretations would promote more helpful public comment. Accordingly, by notice dated June 23, 1993 (58 FR 34024), the Department made available on request a summary of the policies and interpretations in existence prior to 1988. The June notice also extended the public comment period for 45 days, to permit further substantive comment on the prior policies and interpretations. Over a third of the public comments, including the majority of the comments from individuals, were received during the re-opened and comment period. The Secretary has thus addressed the concern about notice of the content of the policies and interpretations expressed by these comments.

As is further discussed below, the Secretary has incorporated in the regulatory text the policies relating to nondirective counseling and referral of the 1981 Program Guidelines for Project Grants for Family Planning Services (1981 Guidelines). The comments urging that these Guidelines requirements be reflected in the regulations have thus been accepted. With respect to the longstanding program interpretations, however, the Secretary does not agree that the Department is required to set out those



interpretations in the regulations promulgated below and accordingly, has not accepted the comments suggesting that it do so. As noted above, the interpretations themselves were developed in the classic way in which statutory interpretations are done: That is, they have generally been developed in legal opinions written to answer questions about how the statutory prohibition, as initially interpreted by the Department, applied to particular situations. This is not an unusual approach within the program as a whole: Interpretive guidance has been provided on a number of issues (e.g., fee schedules, use of certain methods) over the years, as particular questions have arisen in the course of the program. While the program could incorporate those interpretations in the legislative rules below, the Secretary has decided not to do so. With respect to the areas that continue to be covered by guidance, the Secretary believes that incorporating the guidance into the regulations below would be inadvisable and unnecessary. The Secretary has thus chosen to preserve the program's flexibility to address new issues that may arise in this area.

Moreover, the Title X program grantees have operated on the basis of the policies of the 1981 Guidelines and the interpretations summarized in the notice published elsewhere in this issue of the **Federal Register** for virtually the entire history of the program and in general compliance with them. As the comment of one State agency grantee stated with regard to this issue:

The [State] Family Planning Program has been a participant in the nation's Title X program since the early 1970's. The rules and 1981 *Family Planning Guidelines* in place prior to the "Gag Rule" were adequate guidance to the state for program operation and for compliance with the statutory prohibition related to abortions. These guidelines and directives have been used successfully for many years in providing quality medical care, education and counseling to clients in the program.

The audits of 14 Title X grantees conducted by the GAO and of 31 Title X grantees conducted by the Department's Office of the Inspector General in the 1980's showed only minor compliance problems. Indeed, the principal recommendation of both audit reports was that the Department provide more specific guidance to its grantees than that previously available in the program guidelines and prior legal opinions, not that the Department undertake major disallowances, require major corrective actions, or develop new interpretations of the law such as that embodied in the Gag Rule. *See, e.g.,*

Comp. Gen. Rep. No GAO/HARD-HRD-82-106 (1982), at 14-15. The Secretary is addressing this recommendation through the specific guidance in the notice published elsewhere in this edition of the **Federal Register** and believe that the notice will provide grantees with sufficient guidance to reduce or eliminate potential variations in grantee practice.

The Secretary views this final rule, the principal purposes of which are to revoke the Gag Rule and adopt the counseling and referral requirements noted, as separate and severable from the Notice. The interpretations set out in the Notice are being set out in order to clarify the Department's view of the statute and its operation in practical terms, and because so much of the public comment received was directed at the interpretations reflected in the Notice rather than at the revision of the regulation itself. Were the policies set forth in the Notice to be challenged or invalidated, it is our view that the Title X program could still be administered under the rules below in compliance with the statute, in that grantees would be prohibited by § 59.5(a)(5) below from providing abortions as part of the Title X family project and from engaging in counseling and referral practices inconsistent with the regulatory requirements adopted in that section. Such an outcome would be consistent with a permissible interpretation of the statute.

#### *C. Amend, or Adopt a More Restrictive Reading of, the Statute*

Fifteen of the comments that stated support for the proposed policies and interpretations suggested, however, that the prior limitations in the policies and interpretations with respect to what abortion-related activities a Title X project could engage in be eliminated. A few of these comments suggested that the statutory prohibition of section 1008 be repealed outright. Most of the comments suggested in essence that the statute be read strictly to prohibit only the use of funds for abortions, thereby permitting Title X projects to engage in a number of abortion-related activities that would not be permitted under the pre-1988 interpretations.

With respect to the suggestion that section 1008 be repealed, such an action is obviously outside the scope of what can be accomplished through rulemaking and thus cannot be accepted in this context. With respect to the remaining comments, while the Secretary agrees that the statute could on its face be read only to proscribe the use of Title X funds for the provisions of abortion, this is not considered to be

the better reading of the statutory language. Rather, the legislative history of section 1008 indicates that that section was intended to restrict the permissible scope of abortion-related services provided under Title X. Conf. Rep. No. 1667, 97th Cong., 2d Sess. 8-9 (1970). The floor statements by the section's principal sponsor, Rep. Dingell, indicated that the section's restrictions on the "use" of Title X funds should be read as having a broader scope that is urged by these comments:

Mr. Speaker, I support the legislation before this body. I set forth in my extended remarks the reasons why I offered to the amendment which prohibited abortion as a method of family planning \*\*\*. With the "prohibition of abortion" the committee members clearly intended that abortion is not to be encouraged or promoted in any way through this legislation. Programs which include abortion as a method of family planning are not eligible for funds allocated through this Act.

116 Cong. Rec. 37375 (1970). The Department has consistently, since 1972, read section 1008 as incorporating this legislation on activities that "promote or encourage" abortion as a method of family planning. This interpretation is well-known to Congress, which has not, to date amended section 1008. Thus, there is legal support for this longstanding interpretation of the statute. Moreover, there is nothing in the rulemaking record that suggests that this fundamental reading of the statute, as it was administered before the Gag Rule, presented major operational problems for Title X projects. Accordingly, the Secretary has not accepted the suggestions made by this group of comments that section 1008 be read only to prohibit the provision of, or payment for, abortions.

#### *D. Abortion Information and Counseling*

The Gag Rule prohibited the provision of information other than information directed at protecting maternal and fetal health to women determined to be pregnant; thus, it prohibited what is generally known as "options counseling", i.e., the provision to pregnant women in a nondirective fashion of neutral, factual information about all options for the management of a pregnancy, including abortion. *See*, 42 CFR 59.8 (1989 ed.). The pre-1988 policies, in contrast, required options counseling, if requested. As stated in the 1981 "Title X Guidelines":

Pregnant women should be offered information and counseling regarding their pregnancies. Those requesting information on options for the management of an

unintended pregnancy are to be given nondirective counseling on the following alternative courses of action, and referral upon requests:

- Prenatal care and delivery
- Infant care, foster care, or adoption
- Pregnancy termination.

The June, 1993 summary of the pre-1988 interpretations also stated that Title X projects were not permitted to provide options counseling that promoted abortion or encouraged patients to obtain abortion, but could advise patients of all medical options and accompanying risks.

Most of those comments supporting adoption of the proposed rules appeared to agree with the pre-1988 policies and interpretations. However, there appeared to be some confusion among those who agreed with the pre-1988 requirement for options counseling as to how much information and counseling could be provided. Several of these comments also suggested that the “on request” limitation be deleted, particularly where State law requires the provision of information about abortion to women considering that option.

Several comments opposing adoption of the proposed rules and revocation of the Gag Rule also specifically addressed the issue of counseling. Several of these comments suggested that counseling on “all options” include the option of keeping the baby, and two comments suggested that the rules should contain an exception for grantees or individuals who object to providing such information and counseling on moral grounds.

A number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral. These comments recommended that the final regulations include specific language providing for options counseling as a necessary component of quality reproductive health care services. Some cited medical ethics and good medical care as requiring that patients receive full and complete information to enable them to make informed decisions. For example, a leading medical organization commented that all women, regardless of their income level, have a right to full and accurate information about all options for managing an unwanted pregnancy. The organization pointed out that it is essential that the program regulations contain specific language about the counseling and referral requirements, and recommended the incorporation of sections of the 1981 Title X program guidelines into the regulations so as to be absolutely clear that pregnancy counseling and referral

must be provided to patients facing an unwanted pregnancy upon request. Congress has also repeatedly indicated that it considers this requirement to be an important one: the program’s four most recent appropriations, Pub. L. 104–208 (110 Stat. 300–243), Pub. L. 105–78 (111 Stat. 1478), Pub. L. 105–277 (112 Stat. 2681), and Pub. L. 106–113 (113 Stat. 1501–225), required that pregnancy counseling in the Title X program be “nondirective.” Consequently, the Secretary has decided to reflect this fundamental program policy in the regulatory text. *See*, § 59.5(a)(5) below. The interpretive summary has also been revised to reflect this change to the regulation. However, in response to the apparent confusion as to the amount of counseling permitted to be provided under the pre-1988 interpretations, the interpretive summary clarifies that Title X grantees are not restricted as to the completeness of the factual information they may provide relating to all options, including the option of pregnancy termination. It should be noted, though, that the previous restriction as to the “type” of information that may be provided about abortion continues: Information and counseling provided by Title X projects on all options for pregnancy management, including pregnancy termination, must be nondirective. Thus, grantees may provide as much factual, neutral information about any option, including abortion, as they consider warranted by the circumstances, but may not steer or direct clients toward selecting any option, including abortion, in providing options counseling.

The Secretary is retaining the “on request” policy in the regulatory language adopted below, on the ground that it properly implements the requirement for nondirective counseling. If projects were to counsel on an option even where a client indicated that she did not want to consider that option, there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose a particular option. We note that under the “on request” policy a Title X grantee is not prohibited from offering to a pregnant client information and counseling on all options for pregnancy management, including pregnancy termination; indeed, such an offer is required under § 59.5(a)(5) below. However, if the client indicates that she does not want information and counseling on any particular option, that decision must be respected. The regulatory language below reflects this policy. Also, consistent with

longstanding program practice and sound public health policy (see the discussion in the following paragraphs) and to avoid ambiguity in when the offer of pregnancy options counseling must be made, the rule has been clarified to require the offer of pregnancy options counseling to be made whenever a pregnant client presents, not just when the pregnancy is “unintended.”

With respect to the suggestion that counseling on “keeping the baby” be provided, the Secretary views that suggestion as co-extensive with the requirement for the provision of counseling on prenatal care and delivery, as the remaining counseling option set out in the 1981 “Title X Guidelines” and the regulatory language adopted below relates to foster care and adoption. If a more directive form of counseling is meant by this suggestion, it is rejected as inconsistent with the underlying interpretation, recently reinforced by Congress, that counseling on pregnancy options should be nondirective.

Finally, the Secretary rejects the suggestion that an exception to the requirement for options counseling be carved out for those organizations that object to providing such counseling on religious or moral grounds. First, totally omitting information on a legal option or removing an option from the client’s consideration necessarily steers her toward the options presented and is a directive form of counseling. Second, the Secretary is unaware of any current grantees that object to the requirement for nondirective options counseling, so this suggestion appears to be based on more of a hypothetical than an actual concern. Third, the requirement for nondirective options counseling has existed in the Title X program for many years, and, with the exception of the period 1988–1992, it has always been considered to be a necessary and basic health service of Title X projects. Indeed, pregnancy testing is a common and frequent reason for women coming to visit a Title X clinic: in 1995, an estimated 1.1 million women obtained pregnancy tests in Title X clinics. (National Survey of Family Growth, 1995 cycle, special table.) Clearly, a significant number of Title X clients have a need for information and counseling relating to pregnancy. Fourth, this policy is also consistent with the prevailing medical standards recommended by national medical groups such as the American College of Obstetricians and Gynecologists and the American Medical Association. “Guidelines for Women’s Health Care,” American College of Obstetricians and

Gynecologists, 1996 ed., at 65; “Pregnancy Choices: Raising the Baby, Adoption, and Abortion,” American College of Obstetricians and Gynecologists, September, 1993, reviewed December, 1995; “Code of Medical Ethics: Current Opinions with Annotations,” American Medical Association, 199–1997 ed. Accordingly, the Secretary has not accepted this suggestion.

The corollary suggestion, that the requirement to provide options counseling should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds, is likewise rejected. In addition to the foregoing considerations, such a requirement is not necessary: under 42 U.S.C. 300a–7(d), grantees may not require individual employees who have such objections to provide such counseling. However, in such cases the grantees must make other arrangements to ensure that the service is available to Title X clients who desire it.

#### *E. Referral for abortion*

The Gag Rule specifically prohibited referral for abortion as a method of family planning and required grantees to give women determined to be pregnant a list of providers of prenatal care, which list could not include providers “whose principal business is the provision of abortion.” 42 CFR 59.8(a) (1989 ed.). The Gag Rule permitted referral to an abortion provider only where there was a medical emergency. 42 CFR 59.8(a)(2) (1989 ed.). By contrast, the 1981 Guidelines required appropriate referral on request, while the pre-1988 interpretations permitted Title X projects to make what was known as a “mere referral” for abortion; a “mere referral” was considered to be the provision to the client of the name and address and/or telephone number of an abortion provider. Affirmative actions, such as obtaining a consent for the abortion, arranging for transportation, negotiating a reduction in the fee for an abortion or arranging for or scheduling the procedure, were considered to be prohibited by section 1008. The pre-1988 rules (§ 59.5(b)(1)) were interpreted by the agency to require referral for abortion where medically indicated. See, *Valley Family Planning v. State of North Dakota*, 489 F.Supp. 238 (D.N.D. 1980), *aff’d*, 661 F.2d 99 (8th Cir. 1981).

A number of comments, mostly from individuals and organizations supporting revocation of the Gag Rule, suggested modifications of the proposed referral policies and interpretations.

Most of these comments suggested that the content limitations on referrals be broadened, with Title X grantees being permitted to provide other relevant information, such as comparative charges, stage of pregnancy up to which referral providers may under State law or will provide abortion, the number of weeks of estimated gestation, etc. These comments argued that the provision of such factual information does not “promote or encourage” abortion any more than does the provision of the abortion providers’ names and addresses and/or telephone numbers. One comment also suggested that the restriction on negotiating fees for clients referred for abortion conflicts with the requirement to refer for abortion where medically indicated.

Several comments opposing revocation of the Gag Rule also expressed problems with the proposed referral policies and interpretations. A few comments urged that referrals to agencies that can assist clients who choose the “keeping the baby” or adoption options should be required. Another comment criticized the requirement for referral where “medically indicated” as confusing. Revisions suggested were that “self-referrals” for abortion be specifically prohibited, to reduce commercialization and profiteering by Title X grantees who are also abortion providers and that grantees who objected to abortion on moral or religious grounds be permitted not to make abortion referrals.

The Secretary agrees with the comments advocating expanding the content of what information may be provided in the course of an abortion referral. The content (as opposed to action) restrictions of the “mere referral” policy proceeded from an assumption that the provision of information other than the name and address and/or telephone number of an abortion provider might encourage or promote abortion as a method of family planning. The Secretary now agrees, based on experience and the comments of several providers on this point, that the provision of the types of additional neutral, factual information about particular providers described above is likely to do little, if anything, to encourage or promote the selection of abortion as a method of family planning over and above the provision of the information previously considered permissible; at most, such information would seem likely to assist clients in making a rational selection among abortion providers, if abortion is being considered. Moreover, it does not seem rational to restrict the provision of factual information in the referral

context, when no similar restriction applies in the counseling context. Accordingly, the Secretary has revised the interpretations summarized in the notice section to clarify that grantees are not restricted from providing neutral, factual information about abortion providers in the course of providing an abortion referral, when one is requested by a pregnant Title X client.

Consistent with the incorporation of the requirement for nondirective counseling in the regulations, the regulations below also include the remaining requirement from the 1981 Guidelines, the requirement to provide a referral, if requested by the client. As referenced previously, a number of comments argued that the regulatory text should reflect the requirement for nondirective counseling and referral. One comment described the provision of factual information and referral as requested as both a necessary and significant component of the Title X program for many years. Another comment pointed out that the program guideline requirements regarding pregnancy options counseling and referral have been used for many years, are well understood and accepted in the Title X provider community, and should be required services in Title X family planning clinics. Since the services about which pregnancy options counseling is provided are not ones which a Title X project typically provides, the provision of a referral is the logical and appropriate outcome of the counseling process.

The Secretary is not accepting the remainder of the comments on this issue, as they either proceed from a misunderstanding of, or do not raise valid objections to, the regulations and the proposed policies and interpretations. The comment arguing that the restriction on negotiating fees conflicts with the requirement to refer for abortion where medically indicated is based on a misunderstanding of that requirement: in such circumstances, the referral is not for abortion “as a method of family planning” (*i.e.*, to determine the number and/or space of one’s children) but is rather for the treatment of a medical condition; thus, the statutory prohibition does not apply, so there is no restriction on negotiating fees and similar actions. The suggestion that referrals to agencies that can assist clients who choose the options of “keeping the baby” or adoption be required is likewise rejected as unnecessary. Under the regulatory language adopted below, the options of prenatal care and delivery and adoption are options that are required to be part of the options counseling process, so an



appropriate referral for one or the other option would be required, if the client chose one of those options and requested a referral. However, requiring a referral for prenatal care and delivery or adoption where the client rejected those options would seem coercive and inconsistent with the concerns underlying the “nondirective” counseling requirement. The Secretary also rejects the criticism that the provision requiring referral for abortion where medically indicated is undefined and confusing. The meaning of the regulatory requirement for referrals where medically indicated (which applies to all medical services not provided by the project, not just abortion services) has not in the past been a source of confusion for providers, and the Secretary believes that Title X medical personnel are able to make the medical judgments this requirement calls for.

The Secretary likewise rejects the suggestion that “self-referrals” for abortion be banned. Very few current Title X providers are also abortion providers: it is estimated that, over the past decade, the percentage of Title X providers located with or near abortion providers has been at or below five percent, with approximately half of these providers consisting of hospitals. Thus, the issue this comment raises is irrelevant to the vast majority of Title X grantees and the program as a whole. Moreover, with respect to those few grantees that are also abortion providers, some may be the only or one of only a few abortion providers in their service area, making “self-referrals” a necessity in such situations. The Department has no evidence that commercialization and profiteering are occurring in these circumstances; absent such evidence, the Secretary sees no reason to limit or cut off a legal service option for those Title X clients who freely select it. However, the Department will continue to monitor the issue of self-referrals in the Title X program, to forestall the type of problem suggested by these commenters.

Finally, the Secretary rejects the suggestion that the referral requirement not apply to providers that object to it on moral or religious grounds for the same reasons it objected to the same suggestion with respect to counseling.

#### *F. Physical and Financial Separation*

The Gag Rule required Title X projects to be organized so as to have a physical and financial separation from prohibited abortion activities, determined by whether there was “objective integrity and independence [of the Title X project] from prohibited activities.” 42

CFR 59.9 (1989 ed.). This determination was to be based on a case-by-case review of facts and circumstances. Factors relevant to this determination included, but were not limited to, the existence of separate accounting records, the degree of separation from facilities (such as treatment, consultation, examination, and waiting room) in which prohibited activities occurred and the extent of such prohibited activities, the existence of separate personnel, and the extent of the presence of evidence of identification of the Title X project and the absence of identification of material promoting abortion. *Id.*

The pre-1988 interpretations required Title X grantees to maintain physical and financial separation between the Title X project and any abortion-related activities they conducted, in that a Title X grantee was required to ensure that the Title X-supported project was separate and distinguishable from those activities. This requirement was held to go beyond a requirement for the technical allocation of funds between Title X project activities and impermissible abortion activities. However, it was considered permissible for a hospital grantee to provide abortions, as long as “sufficient separation” was maintained, and common waiting rooms were also permissible, as long as no impermissible materials were present. Common staff and unitary filing systems were also permissible, so long as costs were properly allocated and, with respect to staff members, their abortion-related activities were performed in a program that was itself separate from the Title X project. The test, as articulated in the summary made available for comment by the June 23, 1993 notice, was “whether the abortion element in a program of family planning services bulks so large and is so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost.”

These interpretations received by far the most specific and extensive public comment. The vast majority of this public comment was from providers and provider organizations and was negative. Although it was generally agreed that the financial separation of Title X project activities from abortion-related activities was required by statute and, in the words of one comment, “absolutely necessary,” many of these comments objected that requiring additional types of separation would be unnecessary, costly, and medically unwise. The argument was made that the requirement for physical separation

is unnecessary, as it is not required by the statute which, on its face, requires financial separation only. Further, it was argued that since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary. With respect to the issue of cost, it was generally objected that requiring separation of staff and facilities would be inefficient and cost ineffective. For example, one comment argued that—

The wastefulness and inefficiency of the separation requirements is \*\*\* illustrated by the policy which allows common waiting rooms, but disallows “impermissible materials” in them. This puts grantees in the position of having to continuously monitor health information for undefined “permissibility” or to build a separate waiting room just to be able to utilize those materials \*\*\*.

It was argued that these concerns were particularly important for small and rural clinics “that may be the only accessible Title X family planning and/or abortion providers for a large population of low-income women.” Of particular concern for such clinics was the duplication of costs inherent in the separation requirements, as they— cannot afford to operate separate facilities or to employ separate staff for these services without substantially increasing the prices of \*\*\* services. Nor can they offer different services on different days of the week because so many of their patients \*\*\* are only able to travel to the clinic on one day.

Many providers also pointed out that requiring complete physical separation of services would be inconsistent with public health principles, which recommend integrated health care, and would impact negatively on continuity of care. As one comment stated, “women’s reproductive health needs are not artificially separated between services: a woman who needs an abortion may also need contraceptive services, and may at another time require parental care.” Several providers objected in particular that such a separation would, in the words of one comment, “remove \* \* \* one of the most opportune time[s] to facilitate the entry of the abortion patient into family planning counseling, which is at the post-abortion check-up.” It was also pointed out that separation of services would burden women, by making them “make multiple appointments or trips to visit different staff or facilities.” Finally, the separation policy was objected to by several of the comments that otherwise generally supported the proposed rule

as unnecessarily broad, ambiguous, and vague.

Several of the comments opposing the revocation of the Gag Rule and the adoption of the proposed rules likewise objected specifically to the separation requirements, generally on the ground that the pre-1988 policies were vague and unenforceable. Two comments also argued that, if the pre-1988 requirement of physical separation was to be reinstituted, it made no sense to revoke § 59.9 of the Gag Rule in its entirety, as that section of the Gag Rule contained specific standards to implement this requirement; alternatively, it was argued that if the Secretary is going to use different standards to determine whether the requisite physical separation existed, those should be published for public comment.

The Secretary agrees that the comments on both sides of this issue have identified substantial concerns with the pre-1988 interpretations with respect to the issue of how much physical separation should be required between a grantee's Title X project activities and abortion-related activities. The Secretary agrees with the comments that the pre-1988 interpretation that some physical separation was required was unenforceable. Indeed, since the pre-1988 interpretations had held that it was permissible to provide abortions on a Title X clinic site and to have common waiting areas, records, and staff (subject largely to proper allocation of costs), it was difficult to tell just what degree and kind of physical separation were prohibited. As a consequence, the agency attempted to enforce this requirement on only a few occasions prior to 1988. The Secretary does not agree with opponents of the proposed rules, however, who argued that the "physical separation" requirements in § 59.9 of the Gag Rule should be retained on the ground that they provide a necessary clarification of this issue. Although § 59.9 provided ostensibly more specific standards, the fundamental measure of compliance under that section remained ambiguous: "the degree of separation from facilities [in which prohibited activities occurred] and the extent of such prohibited activities," and "[t]he extent to which" certain materials were present or absent. Furthermore, since under § 59.9 compliance was to be determined on a "facts and circumstances" basis, this section of the Gag Rule provided grantees with less specific advance notice of the compliance standards than did the pre-1988 policies and interpretations. Moreover, the change in policy from the more concrete policies proposed during the Gag Rule

rulemaking to the less concrete "facts and circumstances" standard ultimately adopted in the final Gag Rule as a result of the public comment suggests the practical difficulties of line-drawing in this area. In fact, since the Gag Rule was never implemented on a national basis, the precise contours of the compliance standards of § 59.9 were never determined. The Secretary has accordingly not accepted the suggestion from several opponents of the proposed rule that the policies of § 59.9 be retained.

As noted by many of the comments from groups that generally supported the revocation of the Gag Rule, the statute does not on its face require physical separation; rather, by its terms it is addressed to the use of "funds." While the interpretation of the statute by agency counsel on which the requirement for physical separation is based was reasonable, it is not the only possible reading of the statute. Rather, the fundamental question under the statute is, as the agency sees it, whether Title X funds are used by Title X grantees to promote or encourage abortions as a method of family planning in the Title X-assisted project. The Department has traditionally viewed a grant project as consisting of an identified set of activities supported in whole or in part by grant funds. If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that—within the identified set of Title X-supported activities—promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for "physical" separation. Indeed, in the light of the enforcement history noted above, it is not unreasonable to say that the standard of "physical" separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, the practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services. Accordingly, the Secretary has accepted the suggestion of a number of the comments that the requirement for physical separation be dropped; the interpretations summarized in the notice published in the notices section of this edition of the

**Federal Register** are revised accordingly. This decision makes it unnecessary to respond to the remaining comments on the issue.

#### *G. Advocacy Restrictions*

The Gag Rule, at 42 CFR 59.10 (1989 ed.), prohibited Title X projects from encouraging, promoting, or advocating abortion as a method of family planning. This section prohibited Title X projects from engaging in actions to "assist women to obtain abortions or increase the availability or accessibility of abortion for family planning purposes," including actions such as lobbying for the passage of legislation to increase the availability of abortion as a method of family planning, providing speakers to promote the use of abortion as a method of family planning, paying dues to any group that as a significant part of its activities advocated abortion as a method of family planning, using legal action to make abortion available as a method of family planning, and developing or disseminating materials advocating abortion as a method of family planning. The pre-1988 interpretations likewise prohibited the promotion or encouragement of abortion as a method of family planning through advocacy activities such as providing speakers, bringing legal action to liberalize statutes relating to abortion, and producing and/or showing films that tend to encourage or promote abortion as a method of family planning. However, under those prior interpretations, it was considered permissible for Title X grantees to be dues-paying members of abortion advocacy groups, so long as there were other legitimate program-related reasons for the affiliation.

Very few comments were received concerning these proposed interpretations. Those received from persons and entities that generally supported the proposed rules generally argued against the restriction on showing films advocating abortion, on the ground that it was possible to violate this restriction by showing a film that was purely factual and detailed relative risks. The few comments on this part of the policies and interpretations received from those who generally opposed revoking the Gag Rule pointed out the similarity between the advocacy policies articulated in the proposed interpretations and § 59.10 of the Gag Rule and argued that § 59.10 should accordingly be reinstated.

As set out above, the Secretary is of the view the Gag Rule cannot and should not be adopted piecemeal, as recommended by these comments. Moreover, the Secretary is of the view



that the prohibition against dues paying contained in § 59.10 is not required by the statute and does not represent sound public policy. Accordingly, the suggestion that § 59.10 be reinstated has not been adopted. With respect to the criticism of the prohibition against Title X grantees showing films advocating abortion as a method of family planning, it is recognized that the prohibition should not encompass the kind of neutral, factual information that grantees are permitted to provide in the counseling context; the interpretations have been clarified accordingly. To the extent that these comments seek to further liberalize the advocacy restrictions, however, they are rejected as inconsistent with the Secretary's basic interpretation of section 1008.

#### H. Miscellaneous

A number of comments were received on miscellaneous issues. Those comments, and the Secretary's responses thereto, are summarized below.

##### 1. Changes outside the scope of the rulemaking

Several comments were received advocating changes to other sections of the regulations on issues other than the issue of compliance with section 1008. These comments included the following suggestions: that the regulations be revised to permit natural family planning providers to be Title X grantees; that the regulations be revised to prohibit single method providers from participating in Title X projects; that the footnote in the regulation addressing Pub. L. 94-63 be revised to state that the law also forbids coercion to carry a pregnancy to term; that the regulations be revised to deal with recent medical developments, such as HIV or Norplant. All of these suggestions are rejected on the ground that they exceed the scope of the rulemaking because these issues were not the subject of the Notice of Proposed Rulemaking.

##### 2. Audit standards

Several providers urged that the OMB audit standards for Title X projects be revised to reflect the change in the regulations. While this comment is likewise outside the scope of the rulemaking, the Department intends to work with the Office of Management and Budget to revise the program audit standards to reflect the regulations below and the policies and interpretations also being reinstituted.

##### 3. Separation of Powers

Two comments, including one from four members of Congress, argued that the suspension of the Gag Rule violated the separation of powers insofar as it misspent federal tax dollars without amendment to the statute or compliance with the APA. The Secretary disagrees that suspension of the Gag Rule violated either the statute or the APA. The Gag Rule was, in the Secretary's view, a permissible interpretation of the statute, but not the only permissible interpretation of the statute; thus, suspension of those rules (and reinstitution of the Department's longstanding policies and interpretations of the statute) is not inconsistent with the statute. Nor was the suspension action inconsistent with the APA, as the findings which the APA requires be made in such circumstances were made. Finally, the Secretary notes that this issues is now moot, with the publication of the regulations below.

##### I. Technical Amendments

Because the proposed rules proposed the reissuance of the program regulations that were issued in 1980, it was recognized that—

some of the other regulations cross-referenced in the rules below may no longer be operative or citations may need to be updated. However, such housekeeping details will be addressed in the final rules.

58 FR 7464. Further review of the proposed regulations has established that this is indeed the case. Accordingly, a number of technical amendments have been made to the regulations, to delete obsolete statutory or regulatory references or to clarify the existing provisions or incorporate new regulatory or other references made relevant by subsequent changes in the law. A summary of the technical amendments, and the reasons therefor, follows:

1. § 59.2 (*definition of "low income family"*): The reference to "Community Services Administration Income Poverty Guidelines (45 CFR 1060.2)" is changed to "Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2)." This change reflects a change in the law, effected by Pub. L. 97-35, § 673.

2. § 59.2 (*definition of "State"*): The definition of this term is changed to reflect statutory changes regarding the Trust Territories of the Pacific Islands effected by Pub. L. 99-239 (relating to the Federated States of Micronesia, the Marshall Islands, and the Republic of Palau).

3. § 59.5(a)(8): The reference to the "CSA Income Poverty Guidelines" is changed, consistent with and for the

reason set out above with respect to § 59.2 (definition of "low income family").

4. § 59.9: The reference to "Subpart Q" of 45 CFR Part 74 has been deleted, as that subpart has been revoked. A reference to 45 CFR Part 92 has been added, to reflect the requirements at that part that apply by their terms of State and local governments.

5. § 59.10: The references to 42 CFR Part 122 and 45 CFR Part 19 have been deleted, as those parts have been revoked. A reference to 37 CFR Part 401, which applies by its terms, has been added, reflecting a change in the law. The description of 45 CFR Part 74 has been changed, to reflect accurately the current title of that part. A reference to 45 CFR Part 92 has been added, to reflect the requirements at that part that apply by their terms to State and local governments.

6. § 59.11: The word "documented" has been inserted before the word "consent" in this section to clarify what was implicit in this section, that the consent for disclosure must be documented by the project.

7. § 59.12 (*proposed*): The proposed section (which was the prior section relating to inventions and discoveries) has been deleted, as it has been superseded by the government-wide regulations at 37 CFR Part 401, a reference to which has been added to § 59.10. This change has also occasioned the renumbering of the proposed § 59.13.

The above changes are all technical in nature and simply bring the regulations issued below into conformity with current law. They are thus essentially housekeeping in nature, as noted in the proposed rules. Accordingly, and for the reasons set out above, the Secretary finds that public comment on these changes would be impracticable, unnecessary, and contrary to the public interest and that good cause therefore exists for omitting public comment thereon.

#### III. Effective Date

These regulations are adopted effective upon publication, as they meet the conditions for exception from the requirement for a 30-day delay in effective date under 5 U.S.C. 553(d). First, by revoking the Gag Rule, the regulations below relieve the restrictions imposed on grantees' conduct of their Title X projects by the Gag Rule. Second, the policies adopted in the regulations below and the interpretations adopted in conjunction with them are already largely in effect, by virtue of the suspension of the Gag Rule and the reinstitution of the pre-

1988 policies and interpretations effected by the interim rules of February 5, 1993. To the extent this *status quo* is changed by the revision of the policies and interpretations in question, the effect of those revisions is to clarify and simplify certain of the present restrictions, which should make complying with the policies and interpretations easier for grantees than is presently the case. Thus, no useful purpose would be served by delaying the effective date of these regulations, and the Secretary accordingly finds that good cause exists for making them effective upon publication.

#### IV. Analysis of Impacts

The Secretary has examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612), and certifies that this final rule will not have a significant impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act (the Act) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 (adjusted for inflation) in any year. This rule will not result in such an expenditure; consequently, it is not covered by Section 202 of the Act.

Executive Order 13132 requires that a Federalism Assessment be prepared in any cases in which policies have significant federalism implications as defined in the Executive Order. The Department does not intend or interpret this final rule as imposing additional costs or burdens on the States. The Department has evaluated the public comments. Public comments from State and local health departments indicate support for the Title X policies contained in the final rule and the interpretations to ensure the provision of quality medical care and patients' rights to comprehensive services. In the interest of consistent program operation and uniform understanding of the policy, the final rule codifies what has been longstanding program policy and is consistent with current program practice.

The Office of Management and Budget has reviewed this rule pursuant to Executive Order 12866.

#### List of Subjects in 42 CFR Part 59.

Family planning—birth control; Grant programs—health; Health facilities.

Dated: June 28, 2000.

**David Satcher,**

*Assistant Secretary for Health and Surgeon General.*

Approved: June 28, 2000.

**Donna E. Shalala,**

*Secretary.*

### PART 59—GRANTS FOR FAMILY PLANNING

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is hereby revised to read as follows:

#### Subpart A—Project Grants for Family Planning Services

Sec.

59.1 To what programs do these regulations apply?

59.2 Definitions.

59.3 Who is eligible to apply for a family planning services grant?

59.4 How does one apply for a family planning services grant?

59.5 What requirements must be met by a family planning project?

59.6 What procedures apply to assure the suitability of informational and educational material?

59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

59.8 How is a grant awarded?

59.9 For what purposes may grant funds be used?

59.10 What other HHS regulations apply to grants under this subpart?

59.11 Confidentiality.

59.12 Additional conditions.

#### Subpart A—Project Grants for Family Planning Services

**Authority:** 42 U.S.C. 300a–4.

##### § 59.1 To what programs do these regulations apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 3200) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

##### § 59.2 Definitions.

As used in this subpart:

*Act* means the Public Health Service Act, as amended.

*Family* means a social unit composed of one person, or two or more persons living together, as a household.

*Low income family* means a family whose total annual income does not exceed 100 percent of the most recent

Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). “Low-income family” also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

*Nonprofit*, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

*Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

*State* includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

##### § 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

##### § 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

##### § 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods

(including natural family planning methods) and services (including infertility services and services for adolescents). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.<sup>1</sup>

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard of religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion a method of family planning. A project must:

(i) Offer pregnant women the opportunity to provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized

to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subgrantees which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies,

and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

#### **§ 59.6 What procedures apply to assure the suitability of informational and educational material?**

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population

<sup>1</sup> Section 205 of Pub. L. 94-63 states: "Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both."



or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which it is to be made available; and

(v) Establish a written record of its determinations.

**§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?**

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of patients, and, in particular, the number of low-income patients to be served;

(2) The extent to which family planning services are needed locally;

(3) The relative need of the applicant;

(4) The capacity of the applicant to make rapid and effective use of the federal assistance;

(5) The adequacy of the applicant's facilities and staff;

(6) The relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project; and

(7) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

**§ 59.8 How is a grant awarded?**

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompet for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

**§ 59.9 For what purpose may grant funds be used?**

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR Part 74 or Part 92, as applicable.

**§ 59.10 What other HHS regulations apply to grants under this subpart?**

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

- 37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements
- 42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure
- 45 CFR Part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR Part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments
- 45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964
- 45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title
- 45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
- 45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance
- 45 CFR Part 92—Uniform administrative requirements for grants and cooperative agreements to state and local governments

**§ 59.11 Confidentiality.**

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

**§ 59.12 Additional conditions.**

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

[FR Doc. 00-16758 Filed 6-30-00; 8:45 am]

BILLING CODE 4160-17-M



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May 17, 2021

Secretary Xavier Becerra  
United States Department of Health and Human Services  
Hubert H. Humphrey Building, Room 716G  
200 Independence Avenue SW  
Washington, DC 20201

*Re: Ohio and twenty other States' comments regarding proposed rule RIN  
0937-AA11, as set forth in 42 CFR Part 59, 86 Federal Register 19812.*

Dear Secretary Becerra:

Ohio and twenty other States submit these comments in opposition to the notice of proposed rulemaking entitled, "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," set forth at 86 Federal Register 19812 (April 15, 2021), which are meant to implement Title X of the Family Planning Services and Population Research Act of 1970.<sup>1</sup>

**I. THE PROPOSED RULE WILL CAUSE THE DEPARTMENT TO SUBSIDIZE ABORTION IN VIOLATION OF TITLE X.**

Many Americans regard abortion as the murder of a child. Other Americans disagree—they consider abortion to be among the most important of rights. "Federal funding has been the quintessential point of compromise between the opposing factions in this fraught and volatile area."<sup>2</sup> "The elements of the compromise may vary in their detail, but the overall components of compromise have remained quite consistent and clear."<sup>3</sup> "Congress, on the one hand, does not seek to bar or directly restrain the right established by the Supreme Court in *Roe v. Wade* and its progeny."<sup>4</sup> "Congress, on the other hand, seeks to respect those who hold moral or religious objections to the contested practice by withholding federal funds from it."<sup>5</sup>

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<sup>1</sup> 42 U.S.C. §300 *et seq.*

<sup>2</sup> *Mayor of Balt. v. Azar*, 973 F.3d 258, 297 (4th Cir. 2020) (en banc) (Wilkinson, J., dissenting).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*; accord *Rust v. Sullivan*, 500 U.S. 173, 201–02 (1991); *Harris v. McRae*, 448 U.S. 297, 315–17 (1980); *Maher v. Roe*, 432 U.S. 464, 474 (1977); Pub. L. No. 115-31, §§ 613–14, 131 Stat. 135, 372 (2017).





Title X reflects this consensus. Congress enacted Title X in 1970, a few years before the U.S. Supreme Court created a national right to abortion. So, while many States had loosened their abortion laws, many others still restricted the practice as a crime, with limited exceptions. The States and citizens taking that view surely would not have supported family-planning funding that even indirectly supported, or stamped a national imprimatur on, a practice they regarded as criminal. That is why Title X's principal sponsor, Congressman John D. Dingell, offered an amendment to his own bill. He explained:

Mr. Speaker, I support the legislation before this body. I set forth in my extended remarks the reasons why I offered the amendment which prohibited abortion as a method of family planning.... With the "prohibition of abortion" amendment—title X, section 1008—the committee members clearly intend that abortion is not to be encouraged or promoted in any way through this legislation. Programs which include abortion as a method of family planning are not eligible for funds allocated through this act.<sup>6</sup>

That promise—that abortion not be "promoted in any way"—is reflected in 42 U.S.C. §300a-6. That statute prohibits using Title X funds "in programs where abortion is a method of family planning." The Supreme Court, in a decision upholding regulations materially identical to those in the 2019 Rule<sup>7</sup> that the Department now wishes to replace, held that this phrase was ambiguous to at least some extent, as it does not "speak directly to the issues of counseling, referral, advocacy, or program integrity."<sup>8</sup> But the statute's use of the location-focused word "where"—which, in this context, means "at or in the place in which"<sup>9</sup>—makes at least two things clear.

*First*, and contrary to the Proposed Rule,<sup>10</sup> Title X funds must not be used at facilities that make abortion referrals. A facility that makes an abortion referral because the patient wants to manage the size of her family (rather than because of a medical emergency) is a facility at which abortion is treated as one option for managing the size of one's family. And so every such facility is, quite literally, a "program where"—a program at or in the place in which—"abortion is a method of family planning."<sup>11</sup>

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<sup>6</sup> 116 Cong. Rec. 37375 (1970).

<sup>7</sup> Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (March 4, 2019).

<sup>8</sup> *Rust*, 500 U.S. at 184.

<sup>9</sup> Webster's Third New International Dictionary 2602 (1993).

<sup>10</sup> See 86 Fed. Reg. at 19830.

<sup>11</sup> 42 U.S.C. §300a-6.

*Second*, and also contrary to the Proposed Rule,<sup>12</sup> Title X funds cannot be used to support a family-planning program that is located *in* an abortion-providing facility. Every abortion-providing facility is, by definition, a facility “where abortion is a method of family planning.”<sup>13</sup> It follows that every Title X program that shares a physical location with such a facility is a program *where*—a program at or in the location in which—“abortion is a method of family planning.”<sup>14</sup>

The Department cannot deviate from the best reading of the text when it does so to circumvent the statutory provision. And its reasons for deviating from the best reading could not be clearer: the Department, knowing that it cannot *expressly* subsidize abortion, plans to do so indirectly by putting Title X services and abortion services in the same place. Courts reviewing administrative actions are “not required to exhibit a naiveté from which ordinary citizens are free.”<sup>15</sup> And when the time comes to review this rule, if it is finalized, they will not.

## **II. THE DEPARTMENT HAS NOT JUSTIFIED THE NEED FOR ANY ALTERATION TO THE TITLE X RULE.**

The Proposed Rule is premised on the idea that, in order to have a successful Title X program, the 2019 Rule must be repealed and replaced. The premise is false: the Department has not sufficiently investigated the effects of the 2019 Rule; there is no reason to suspect that Title X can succeed only by stealthily subsidizing the provision of abortions; and much of the support for the Proposed Rule crumbles with the slightest examination.

### **A. The Department does not have sufficient data to assess the effects of the 2019 Rule.**

The Department has tried to justify the Proposed Rule almost exclusively with reference to the purported effects of the 2019 Rule.<sup>16</sup> But the Department does not, and could not conceivably, have data sufficient to support its conclusion that the current rule is inadequate.

The 2019 Rule took several steps to “ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning and related statutory requirements.”<sup>17</sup> For example, the 2019 Rule permits (but does not require) non-directive consulting about the availability of abortion.<sup>18</sup> It also re-

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<sup>12</sup> See 86 Fed. Reg. at 19818.

<sup>13</sup> 42 U.S.C. §300a-6.

<sup>14</sup> *Id.*

<sup>15</sup> *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2575 (2019).

<sup>16</sup> See 84 Fed. Reg. 7714.

<sup>17</sup> *Id.* at 7714.

<sup>18</sup> *Id.* at 7716–17.

quires Title X recipients to maintain strict physical and financial separation between abortion services and programs that spend Title X money.<sup>19</sup> The 2019 Rule says that “to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities. Mere bookkeeping separation of Title X funds from other monies is not sufficient.”<sup>20</sup>

The Department claims the 2019 Rule is not working. But how could it know? The 2019 Rule required grantees to comply with most requirements, such as the financial-separation requirement, by July 2019. But it delayed the compliance date for physical separation of abortion services to March 4, 2020. Rather than comply with the updated regulations, some entities—notably Planned Parenthood, which operates more than 600 clinics—left the program entirely before the 2019 Rule was fully implemented. And on the heels of the March 4 implementation date, the COVID-19 pandemic wreaked havoc on the healthcare industry. Not only were clinics forced to end elective procedures, but the many safety-related restrictions in cities across the country created barriers for people seeking family-planning services—barriers having no relation whatsoever to Title X.

Combining the newness of the 2019 Rule with the complications caused by COVID-19 means the data could not possibly be sufficient to conclude that the 2019 Rule is not working. The COVID-19 pandemic is a particularly complicating factor. It interfered with the provision of nearly *all* services, medical and otherwise, in the American economy. Even many elective and non-elective medical procedures having nothing to do with family planning or abortion were delayed.<sup>21</sup> Thus, even if there were some reason to think that Title X services will decline because of the 2019 Rule—and there is not<sup>22</sup>—the Proposed Rule wrongly assumes that any such decline would remain after we emerge from the pandemic and after Title X grantees become experienced in dealing with the now-in-effect 2019 Rule.

The Department made a reasoned decision in 2019 to align the Title X program with the law. Today, the facts are not sufficiently developed to allow for a meaningful assessment of the 2019 Rule’s likely effects. But they will be. Given that individuals are just now, in many areas of the country, starting to leave their homes and seek elective services, and given that state budgets and other sources of funding are being replenished, the 2019 Rule will soon be implemented and the Department can compare apples to apples. Ohio requests that the Department study the effects of the 2019 Rule from January 1, 2022, through December 31, 2022, to form a reasoned basis for decision.

<sup>19</sup> *Id.* at 7763–77; 42 C.F.R. §59.15.

<sup>20</sup> 42 C.F.R. §59.15.

<sup>21</sup> See *Non-Emergent, Elective Medical Services, and Treatment Recommendations*, Centers for Medicare and Medicaid Services (April 7, 2020), <https://perma.cc/6FVT-JAPN>.

<sup>22</sup> See *below* 5–13.

**B. The Proposed Rule incorrectly assumes that linking abortion to family-planning services is critical to a vibrant Title X program.**

1. The Proposed Rule does not account for successful programs in the States that have long separated Title X funds and abortion services. Many States administer their own public-health programs without funding abortion providers. And many States administer Title X programs themselves, effectively, without providing or promoting abortions. The Proposed Rule concocts a link between the success of Title X's family-planning mission and the comingling of abortion and Title X funds. In particular, by eliminating the prohibition on providing Title X services in facilities that provide abortion services, the Proposed Rule assumes that Title X can thrive only if abortion providers assist in the distribution of Title X services. But that is wrong.

Most Title X funds support state agencies and county health departments.<sup>23</sup> Many of these public programs provide no elective abortion services, indeed, many operate pursuant to laws that *prohibit* using federal pass-through dollars to indirectly subsidize elective abortion.<sup>24</sup> Yet they are indisputably able to serve the public nonetheless, providing precisely the services that Title X is designed to fund. For example, in Alabama, the State Department of Public Health is the sole Title X grantee.<sup>25</sup> It uses Title X funds to support 80 health centers across the State, all of which are operated by state and local county health departments.<sup>26</sup> These local health centers provide contraceptive services, pelvic exams, screening for STDs, infertility services, and health education. Alabama's 2019 grant award was over \$5,000,000, which it used to provide services to roughly one hundred thousand people.<sup>27</sup> Alabama's health centers do not provide abortions. Nor do they share office space with providers that do. Yet those health centers are still able to provide precisely the services that Title X envisions. There is no reason to doubt that this model can work across the country. So there is every reason to doubt whether a successful Title X program requires allowing abortion providers to offer Title X programs—reality shows that States and other grantees can easily separate the services.

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<sup>23</sup> See *Title X Family Planning Directory*, OASH Office of Population Affairs (Mar. 2021), <https://perma.cc/8C75-K7XJ>; see also *HHS Awards Title X Family Planning Service Grants*, OASH Office of Population Affairs (March 29, 2019), <https://perma.cc/VY8D-QH4F>.

<sup>24</sup> See, e.g., Ariz. Rev. Stat. Ann. §35-196.02; Colo. Rev. Stat. Ann. §25.5-3-106; La. Rev. Stat. §40:1061.6; Iowa Code Ann. §217.41B; Miss. Code. Ann. §41-41-91; Mich. Comp. Laws Ann. §400.109a; Mo. Ann. Stat. §188.205; N.C. Gen. Stat. Ann. §143C-6-5.5; Ohio Rev. Code §5101.56; Tex. Health & Safety Code Ann. §32.005; Wis. Stat. Ann. §20.927.

<sup>25</sup> See *Title X Family Planning Directory*, OASH Office of Population Affairs (Mar. 2021), <https://perma.cc/8C75-K7XJ>.

<sup>26</sup> See *id.*

<sup>27</sup> See *HHS Awards Title X Family Planning Service Grants*, OASH Office of Population Affairs (Mar. 29, 2019), <https://perma.cc/VY8D-QH4F>.



The Proposed Rule entirely fails to explain the successful Title X programs coming from these States, and instead resorts to bald assertions that Title X requires a close connection with abortion services to be successful.

2. The Proposed Rule also assumes that any gaps created by abortion providers who left the Title X program in response to the 2019 Rule will be permanent. That assumption is baseless. It ignores the fact that, when abortion providers like Planned Parenthood left Title X in 2019, other providers stepped in to fill gaps in coverage. Ohio's experience illustrates the point. In Ohio, before the 2019 Rule went into effect, only two grantees received money through the Title X program: Planned Parenthood and the State of Ohio. (The State then subgranted the funds to other entities, including, for example, county boards of health.) In March 2019, Planned Parenthood of Greater Ohio was awarded \$4 million, and the Ohio Department of Health was awarded \$4.3 million.<sup>28</sup> Once the new rules went into effect, however, Planned Parenthood left the program because it did not wish to comply with the 2019 Rule.<sup>29</sup> That, however, did not leave a gap in coverage. That is because, as the Department knows, it took the funds that Planned Parenthood affiliates relinquished and granted \$33.6 million in supplemental funds to Title X grantees. In Ohio, *all* of the funding that would otherwise have gone to Planned Parenthood went to the Ohio Department of Health instead.<sup>30</sup> And Ohio used the new money to expand its provision of Title X services in areas previously served by Planned Parenthood.

What this shows is that there are plenty of actors, including the States themselves, eager to participate in the program envisioned by Title X. (To the extent there are some gaps that remain to be filled, there is no reason to assume those gaps will remain as States and providers emerge from the pandemic and become accustomed to the 2019 Rule.) The Department need not choose between providing Title X services and indirectly supporting abortion: it can have both, by letting entities that do not wish to subsidize abortion provide the services Congress intended.

**C. The Proposed Rule does not adequately justify its abandonment of the 2019 Rule.**

Perhaps not surprisingly given the dearth of data and the States' long experience showing that the 2019 Rule is perfectly consistent with a successful Title X program, the Proposed Rule contains no adequate justification for jettisoning the now-existing regulations. Worse, the justifications it does give all fail.

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<sup>28</sup> *Id.*

<sup>29</sup> See *California v. Azar*, 950 F.3d 1067, 1099 n.30 (9th Cir. 2020) (*en banc*).

<sup>30</sup> See *HHS Issues Supplemental Grant Awards to Title X Recipients*, OASH Office of Population Affairs (Sept. 30, 2019), <https://perma.cc/5XF5-MAER>.

1. *The Proposed Rule does not adequately identify or explain negative health consequences.*

The Proposed Rule attempts to describe “large negative public health consequences” for maintaining the existing Rule.<sup>31</sup> Such consequences are conjecture, and are not supported by the facts in the Proposed Rule. To the extent that the United States in 2019 experienced a decline in Title X services, the Proposed Rule fails to explain likely causes, and thus fails to address those causes in any policy alternatives.

a. As its primary justification, the Proposed Rule explains that fewer Title X services were provided in 2019 than 2018. That is a red herring. That fact speaks only to the size of a federal program, and not to the availability or quality of family-planning services for Americans. The bureaucratic illogic goes like this: the bigger the federal program, the better for Americans. That cannot be the case. If a city has fewer police encounters in a given year, that is likely good thing, indicating less crime. If Medicaid has fewer enrollees, that too may indicate increased health, prosperity, or the fact that the Medicaid-eligible population prefers other options. The relevant question for Title X is not whether the program provided fewer services, but whether Americans’ reproductive health is better. The Proposed Rule fails to consider that issue, instead baselessly assuming that bigger is better.

Concerningly, the Proposed Rule assumes that 181,477 unintended pregnancies have resulted from the 2019 Rule, in a single year. The facts do not bear this out. First, the rate of contraception use increased in every State between 2017 and 2019, and many of these methods are long-term or permanent.<sup>32</sup> That increased use would indicate that unintended pregnancies decreased in 2019. Moreover, as the Proposed Rule says, 47 percent of unintended pregnancies result in unplanned births.<sup>33</sup> But the birthrate in 2020 fell to its lowest level in more than 40 years, with the decline occurring across every age and race.<sup>34</sup> The Proposed Rule’s justification—that replacing the 2019 Rule is necessary for public health—is built on irrelevant and apparently false information.

In addition, the Proposed Rule speculates that the 2019 Rule threatened public health, but fails to acknowledge, let alone explain, concerning health trends that far pre-date the 2019 Rule. These trends may be continued or accelerated by the resuscitation of the 2000 Rule.<sup>35</sup> For example, in 2018, the Centers for Disease Control

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<sup>31</sup> 86 Fed. Reg. at 19817.

<sup>32</sup> Ayana Douglas-Hall, Naomi Li, & Megan L. Kavanaugh, *State-Level Estimates of Contraceptive Use in the United States, 2019*, Guttmacher Institute (Dec. 2020), <https://perma.cc/NRS7-9T4B>.

<sup>33</sup> 86 Fed. Reg. at 19823–24.

<sup>34</sup> Brady E. Hamilton et al., *Births: Provisional Data for 2020*, National Center for Health Statistics (May 2021), <https://www.cdc.gov/nchs/data/vsrr/vsrr012-508.pdf>.

<sup>35</sup> Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41269 (July 3, 2000).

and Prevention reported that STDs were at a record high.<sup>36</sup> The Proposed Rule does not indicate why it prefers to restore the policy that was in place when America reached this unfortunate peak.

**b.** The decrease in Title X services is likely explained, in whole or in part, by other causes. The Proposed Rule does not address them.

In simply examining the number of services provided, the Proposed Rule fails to weigh the significance of Planned Parenthood's, and other grantees', exit from the program. They declined Title X funds entirely rather than complying with the 2019 Rule. These decisions may explain most, if not all, of the Title X service reduction. Planned Parenthood served *more* individuals in 2019 than the prior year, further undermining the notion that access to certain services is threatened by the existing rule. For example, the Proposed Rule explains that 90,386 fewer Papanicolaou (Pap) tests were conducted in 2019 than 2018. But Planned Parenthood says that it performed 255,682 Pap tests in fiscal year 2018–2019 and 272,990 tests in fiscal year 2019–2020.<sup>37</sup> These numbers indicate that it is more likely that women continued to get tested, not that fewer Pap tests were performed in the United States— from a health perspective, it does not matter whether women receive tests in or outside of the Title X program. And as discussed above, *even if* there were a dropoff in the use of Title X services after the adoption of the 2019 rule, that alone does not justify assuming the dropoff will remain permanent as new grantees enter the program and as all grantees adjust to the 2019 Rule, all while patients return to something approaching their pre-pandemic lives.

In addition, of the women served through Title X in 2019 using contraception methods, 19 percent used more reliable, either long-acting or permanent, contraceptive methods, reducing the need for annual or more frequent visits.<sup>38</sup> In fact, the number of women using the most effective methods of contraception has increased 50 percent since 2009.<sup>39</sup>

Also, Title X is most commonly used by young, low-income individuals, many of whom are uninsured.<sup>40</sup> In 2019, median household income rose 6.8 percent from 2018.<sup>41</sup> Thus, individuals who previously used Title X services may today use a primary care provider or gynecologist through private insurance. Also, to the extent

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<sup>36</sup> *National STD Trends: Key Information on Sexually Transmitted Diseases for Public Health Leadership*, Association of State and Territorial Health Officials, <https://perma.cc/G58R-WBEW>.

<sup>37</sup> See Planned Parenthood, Annual Report 2018-2019, <https://perma.cc/T7U8-U32G>; Planned Parenthood, Annual Report 2019-2020, <https://perma.cc/9V7W-AAXJ>.

<sup>38</sup> Christina Fowler et al., *Family Planning Annual Report: 2019 National Summary*, OASH Office of Population Affairs, at ES-3 (Sept. 2020), <https://perma.cc/Z9HF-EHV4>.

<sup>39</sup> *Id.* at 30.

<sup>40</sup> *Id.* at 10, 23–24.

<sup>41</sup> Jessica Semega et al., *Income and Poverty in the United States: 2019*, U.S. Census Bureau (Sept. 15, 2020), <https://perma.cc/WE7T-Z387>.

contraception is continually becoming more common, a young person may today visit her parents' physician or use her parents' insurance, when previously she would have avoided that interaction.

The healthcare market has also recently become more diverse, adding options like One Medical, a membership-based primary care option with more than 500,000 members.<sup>42</sup> Individuals in search of an affordable, non-insurance-based outpatient clinic have new options beyond Title X clinics.

Notably, the number of Title X services has been declining since 2010. The Proposed Rule, following its own logic, must explain why it readopts much of the 2000 Rule as purportedly better than the 2019 Rule, when the 2000 Rule coincided with declining services (and declining health outcomes, too) for a longer period of eight years—without a pandemic.

To be clear, neither the States nor anyone else can say with much confidence *why* the number of services has declined. Nor can the States or anyone else predict with much confidence whether the trend will continue. The 2019 Rule has been in effect for so short a time period, and its effects are complicated by so many variables (including a once-in-a-lifetime pandemic), that everyone needs more time to understand the likely effects of the 2019 Rules. What we do know, however, is that the Department has no basis for assuming that a decrease in the provision of services, which occurred in the midst of a global pandemic and during the transition to a new regulatory scheme, will be permanent, and the Department has no clear evidence of its impact on patient health.

c. Having identified its concerns with the 2019 Rule, the Department asserts that it considered two regulatory alternatives to address them: (1) maintaining the 2019 Rule and adding more grantee oversight; or (2) re-adopting the 2000 Rule and adding even more grantee flexibility. But these alternatives do not actually meet the regulatory goals of the Proposed Rule, exposing that the Department did not actually consider policy alternatives.

The Department purportedly seeks to: (1) mimic the number of services provided during the 2000 Rule, (2) improve public health, and (3) decrease compliance costs for grantees. The Proposed Rule then explains that one alternative would be to “impose additional restrictions on grantees.”<sup>43</sup> This is not an alternative means to seek the benefits the Department outlines. If the Department believes that grantee compliance costs are too great, then realistic policy alternatives would include: dedicating funds to assist grantees with those costs, providing additional runway for grantees to comply, giving additional guidance to clarify restrictions, or granting

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<sup>42</sup> *One Medical Announces Results for Third Quarter 2020* (Nov. 10, 2020), <https://perma.cc/4926-ZJGY>.

<sup>43</sup> 86 Fed. Reg. at 19827.

targeted exceptions for those Title X programs in need of flexibilities. The Proposed Rule does not indicate that the Department considered these or any other alternatives for meeting, rather than frustrating, its stated goals.

Incidentally, the second alternative—“reducing programmatic oversight”—is entirely unexplained. It is impossible for the public to contemplate benefits of an alternative void of content.

2. *Removing the physical and financial separation requirements will result in the misuse of funds.*

The Proposed Rule removes the 2019 Rule’s physical and financial separation requirements on the basis that the requirements provide no benefits. But the Department’s failure to identify misused grant funds between 1993 and 2019 proves the need for greater, not lesser, oversight. On one hand, the Proposed Rule indicates only that “no diversion” was uncovered “that would justify” increased separation requirements.<sup>44</sup> To the extent the Department *is* aware of funds being diverted during that time, the Proposed Rule fails to explain why such instances do not justify keeping the 2019 Rule. On the other hand, if the Department never uncovered impermissible transfer or commingling of funds between 1993 and 2019, this emphasizes the need for greater separation, recordkeeping, and oversight: it is simply implausible that, during that long period of time, no funds were misused. (To take an analogy, if a State recorded no positive COVID tests in 2020, that would indicate a failure to test correctly, not the absence of disease.)

Moreover, fund diversion or misuse is nowhere defined or explained. At what point does the Department care whether Title X funds and other revenue sources are treated as one pot of funds? May a Title X project and a non-Title X project share rent, even if the services performed under that roof are most commonly abortion services? If a doctor receives half her salary from Title X funds but spends 80 percent of her time performing abortions, is that a permissible or impermissible commingling of funds? The Department must clarify. If the Department believes a grantee can commingle funds without consequence—for example, pay for 99 percent of the salary of an abortion doctor—this scheme violates the statute. If the Department has a line that grantees may or may not cross, the line must not be arbitrary. And if the Department agrees in theory such commingling is impermissible, but in practice fails to enforce the statute, it violates its responsibility to help the President fulfill his constitutional duty to take care that the laws be faithfully executed. In other words, the answer to potential problems with enforcing the statutory mandate is to find *better methods to enforce* that mandate, not to ignore the mandate with a deliberately blind eye.

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<sup>44</sup> *Id.* at 19816.



3. *The Proposed Rule risks deterring women from seeking family-planning services.*

Removal of the 2019 Rule's physical separation requirements could also undermine the Department's purported goals of increasing services and improving public health. For a variety of reasons, many individuals might prefer to receive Title X services at a location that does not also perform abortions. Individuals who believe abortion takes an innocent life likely would not wish to enter a mixed-use Title X facility. Even individuals who are themselves in favor of abortion as a policy matter or who have had abortions in the past might experience discomfort when directly exposed to a vacuum that removes parts of a child in the womb while receiving a Pap test or STD examination.<sup>45</sup> Rather than increase the provision of Title X services, the Proposed Rule is likely to deter individuals from seeking those services in the first place.

4. *The Congressional Review Act forecloses the Proposed Rule's misguided attempt to limit State laws governing subrecipients.*

Multiple States have laws that restrict state family-planning funding, including federal funding that passes through the State, from being used to pay for abortions.<sup>46</sup> And some States further restrict family-planning funds from organizations that provide abortions, that contract with abortion providers, or that refer patients to get abortions.<sup>47</sup> These laws have permitted these States to operate family-planning services that generate broad public support, and avoid divisive and unproductive fights that may have required some States to eliminate public funding of family-planning services entirely.

In 2016, in the last days of the Obama Administration, the Department published a final rule targeting state laws governing Title X subawards. That rule provided: "No recipient making subawards for the provision of services as part of its Title X project may prohibit an entity from participating for reasons other than its ability to provide Title X services."<sup>48</sup>

But Congress quickly nullified this "Midnight Rule" under the Congressional Review Act.<sup>49</sup> And under the Congressional Review Act, the Department may not reis-

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<sup>45</sup> *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007).

<sup>46</sup> See, e.g., Ariz. Rev. Stat. Ann. §35-196.02; Colo. Rev. Stat. Ann. §25.5-3-106; La. Rev. Stat. §40:1061.6; Iowa Code Ann. §217.41B; Miss. Code. Ann. §41-41-91; Mich. Comp. Laws Ann. §400.109a; Mo. Ann. Stat. §188.205; N.C. Gen. Stat. Ann. §143C-6-5.5; Ohio Rev. Code §5101.56; Tex. Health & Safety Code Ann. §32.005; Wis. Stat. Ann. §20.927.

<sup>47</sup> See Ark. Code Ann. §20-16-1602; La. Rev. Stat. §49:200.51; Ind. Code Ann. §5-22-17-5.5; Wis. Stat. Ann. §253.07(5).

<sup>48</sup> 81 Fed. Reg. 91852 (Dec. 19, 2016).

<sup>49</sup> Pub. L. No. 115-23, 131 Stat. 89 (Apr. 13, 2017).

sue the rule in “substantially the same form.”<sup>50</sup> The Proposed Rule’s invitation for comment regarding “some state policies restricting eligible subrecipients” targets exactly the same state laws as the 2016 Midnight Rule.<sup>51</sup> Thus, any final rule accomplishing what the Proposed Rule suggests may not be issued.

Not only would re-issuing the 2016 Midnight Rule violate the Congressional Review Act, it would also impermissibly intrude on the States’ self-governance for no good reason. As explained above, the States have successfully implemented family-planning projects because they are able to maintain a degree of separation from publicly funded abortions, an issue that would garner enormous public outcry and threaten those States’ existing programs.

5. *The 2019 Rule creates no ethical problems that need to be addressed, but the Proposed Rule will create ethical problems.*

The Proposed Rule suggests that it is important to permit abortion referrals and abortion counseling because such referrals and counseling are required by “ethical codes of major medical organizations.”<sup>52</sup> But it is of no moment whether most or all medical organizations regard the 2019 Rules as contrary to medical ethics. Indeed, medical organizations represent doctors—the parties *regulated by* rules of medical ethics. While regulated entities are no doubt entitled to their opinions on the rules to which their conduct ought to be subject, the regulators are free to reject those opinions. And to the extent the medical profession as a whole thinks it is unethical to refuse to make an abortion referral, that view is *contrary to* the rules of medical ethics reflected in numerous state and federal laws, which say that doctors *may* refuse to make abortion referrals or otherwise participate in the provision of abortions.<sup>53</sup> The States regulate the ethics of the medical profession; the profession does not simply regulate itself.

Moreover, it is doubtful whether the medical organizations who shared their concerns truly do reflect the views of the medical profession as a whole. Surely they do not represent the views of the American Association of Pro-Life Obstetricians & Gynecologists, or the Christian Medical and Dental Associations.<sup>54</sup> And one of the medical organizations that has expressed concerns with the ban on referrals—the American Association of Obstetricians and Gynecologists—has filed briefs defending

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<sup>50</sup> 5 U.S.C. §801(b)(2).

<sup>51</sup> 86 Fed. Reg. at 19817.

<sup>52</sup> *Id.*

<sup>53</sup> See, e.g., Ariz. Rev. Stat. §36-2154(A); Conn. Agencies Regs. §19-13-D54(f); Fla. Stat. §390.0111(8); Id. Code §18-612; Ky. Rev. Stat. §311.800(4); La. Rev. Stat. §40:1061.2; Mont. Code Ann. §50-20-111(2); N.Y. Civ. Rights Law §79-i; Ohio Rev. Code §4731.91; Or. Rev. Stat. §435.485; 18 Pa. Cons. Stat. §3213(d); Wis. Stat. §253.09(1).

<sup>54</sup> See Br. of Amici Curiae Am. Ass’n of Pro-Life OBGYNs, et al., in Support of Petitioners *Azar v. Mayor and City Council of Balt.*, No. 20-454 (U.S., Nov. 9, 2020).

the legality of eugenic abortions.<sup>55</sup> Those willing to stand up for eugenics ought not be taken seriously in any discussion of ethics.

As all this shows, any change to the rules that will require counseling or referrals on abortion will *contradict* medical ethics: as state laws from around the country show, it is unethical to mandate that doctors violate their consciences by endorsing or otherwise participating in abortions.

### III. CONSIDERATION OF TECHNICAL CONCERNS.

Several of the definitions in the Proposed Rule are unclear and put grantees in jeopardy of violating federal law.

**Clarify “health equity.”** The Proposed Rule requires applicants to advance health equity. The Proposed Rule does not explain how this requirement differs from existing considerations and requirements in Title X grantmaking. All applicants must already indicate the number of patients served and the extent to which family-planning services are needed locally, and grant priority is given to projects that serve low-income families. In addition, health programs that receive funding from the Department may not discriminate on the basis of race, color, national origin, sex, age, or disability.<sup>56</sup> Thus existing law requires nondiscriminatory treatment, aimed to those patients most in need. To the extent promoting health equity merely reiterates these requirements, such clarification is useful. To the extent promoting health equity differs, and either requires discrimination on the basis of race or should not be aimed at certain patients, such clarification would be necessary though likely contrary to law.

**Remove “culturally and linguistically appropriate services.”** Ohio and the signing States fully support the principle that Title X services should be available to individuals regardless of their culture or language. At the same time, States owe a duty to our citizens to put science and health before any interest in the signaling of virtue. As the Department’s existing standards for “culturally and linguistically appropriate services” indicate, the many elements of culture include the “use of traditional healer techniques,” “how an individual finds and defines meaning in his life,” and “political beliefs.”<sup>57</sup> Requiring unique health approaches that differ based on the individual belief system of every American is not only impossible, in many cases, it can also be unwise. For example, obesity, smoking, and drug use are

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<sup>55</sup> See Brief for Am. Coll. of OBGYNs, et al., as Amici Curiae in Support of Appellees, *Preterm-Cleveland v. McCloud*, 994 F.3d 512 (6th Cir. 2021) (No. 18-3329).

<sup>56</sup> 42 U.S.C. §18116.

<sup>57</sup> *National Standards for Culturally & Linguistically Appropriate Services in Health & Health Care*, U.S. Dep’t of Health & Human Servs. Office of Minority Health at 139–40 (April 2013), <https://perma.cc/F8YE-PJVV>.

health and reproductive risks, no matter the culture or language of the patient seeking services.

To the extent certain populations require targeted approaches to improve health outcomes, that approach is best managed and executed at the state and local level. As it exists in the Proposed Rule, the phrase “culturally and linguistically appropriate services” may bless health practices, based on cultural norms, that lead to negative health outcomes. Ohio therefore recommends removing the phrase as a requirement in Title X grants. The States, as always, will remain passionate about providing the care that their citizens need and deserve.

***Amend “quality healthcare.”*** Improving the quality of healthcare in America must be a dynamic process, constantly employing new techniques, identifying threats, preserving privacy, expanding comfort, and decreasing waste and inefficiency. This dynamism requires a nimbleness often unattainable by national requirements, which are slow to adopt useful techniques or recognize local problems. Thus “quality healthcare” should be amended as follows: “Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable, with maximum flexibility at the state and local level to establish standards of care.”

\* \* \*


In a country of more than 300 million people, no one gets his or her way all the time. Everyone has to compromise a bit. Title X reflects a compromise. It funds services that large numbers of Americans support while withholding that funding from services that large numbers oppose. The Proposed Rule tramples that compromise, by intertwining family-planning services with the divisive issue of publicly funded abortions. The Proposed Rule is not based on the public health, but grantee preference to have freer rein of taxpayer dollars.

Sincerely,

A handwritten signature in blue ink that reads "Dave Yost". The signature is fluid and cursive, with the first name "Dave" and last name "Yost" clearly distinguishable.


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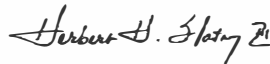
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**U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Office of Population Affairs**

Tennessee Department of Health  
**FPHPA006553**  
Title X Program Review Report

**Virtual Program Review (VPR)  
July 11-15, 2022**

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## Grantee Information

**Grantee Name:** Tennessee Department of Health

**Grantee Number:** FPHPA006553

**Project Period:** April 1, 2022 to March 31, 2027

**Budget Period:** April 1, 2022 to March 31, 2023

Federal Share: \$7,108,750

Non-federal Share: \$8,594,213

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Total: \$18,627,963

Program Income: \$0

**Project Director:** Danni Lambert

**Project Address:** 710 James Robertson Pkwy, 64 Andrew Johnson Tower  
Family Health and Wellness  
Nashville, TN 37243

**Virtual Visit Dates:** July 11-15, 2022

**Service Sites Visited:** **Telehealth**

710 James White Parkway, Nashville TN 37243

**Hamilton Clinic**

Main 921 E. 3<sup>rd</sup> Street Chattanooga, TN 37403

**Polk County Benton Clinic**

2279 Parkside Road, Benton, TN

**Review Team:** Tisha Reed – OPA Project Officer  
Joyce McIntyre – Administrative Reviewer  
Karen Ward – Clinical Reviewer  
Valerie Butt – Fiscal Reviewer

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## Overview of the Project

The Tennessee Family Planning Program (TFPP) is a Tennessee Department of Health program that has served as a Title X grantee since 1972. The Tennessee Department of Health has a strong public health infrastructure to provide administrative, clinical and financial management support to a network of 124 sites providing family planning services across all 95 counties in the state. If funded, at least 75% of clients will be at or below 100% of the Federal Poverty Level. The TFPP provides services that are client-centered, culturally and linguistically appropriate, inclusive, and trauma informed. The TFPP works to protect the dignity of the individual and ensure equitable and quality service delivery. Tennessee Family Planning Program services encompass a broad range of medically approved family planning methods ranging from abstinence, sterilizations and LARCs to natural family planning and fertility awareness based methods, pregnancy testing and counseling, achieving pregnancy, basic infertility services, preconception and interconception care, and STD/HIV testing and treatment. Multiple sites also provide primary care, preventive health and dental services. The TFPP provides confidential services to minors, promotes parental involvement, and complies with all Title X and state requirements regarding mandatory reporting. Abstinence (sexual risk avoidance) and counseling related to coercive relationships is also provided to all adolescent clients and others as appropriate. As a leading expert on family planning service delivery, the TFPP has established partnerships with community-based and faith-based organizations that enhance clients' ability to achieve optimal health outcomes. The Tennessee Department of Health is the only agency with the capacity, staff, and expertise to administer Title X funds with integrity and without a gap in services in the state of Tennessee.

### **The Title X Virtual Program Review Process and Review Tool**

OPA notified the grantee of the program review, held July 11-15, 2022, earlier this year. Due to the COVID pandemic and response across the nation, the traditional in-person program review shifted to be a virtual program review (VPR). OPA requested the grantee to provide certain materials (policy and procedure manuals, etc.) in advance of the review by using the MAX.gov platform. OPA also provided the grantee with a copy of the OPA program review tool, updated with the Title X 2021 new rule. This tool is the instrument used by the review team during the VPR.

The review team utilized the tool to systematically observe and evaluate program operations, seeking evidence of compliance with the Title X regulations and implementation of the Quality Family Planning recommendations.

#### *Assessment of Compliance with Title X Program Expectations*

This assessment evaluated the grantee's compliance with the statute, regulations, legislative mandates, and OPA expectations governing the Title X grant program. For these expectations, the grantee received an assessment of compliance and a rating of "met," "not met," or "N/A" (not applicable). The evidence of meeting minimum criteria was determined based on both grantee and subrecipient records and observation at grantee administrative offices and selected service sites as part of the VPR process. Evidence may include but is not limited to, policies, procedures, protocols, documentation of training, direct visual confirmation per review team consultants and/or OPA staff

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to ensure that what is contained in written policy is actually implemented, or any other form of documentation that substantiates that the project is operating in accordance with the Title X Program expectations.

#### *Assessment of the Implementation of the Quality Family Planning Recommendation*

This assessment evaluated the extent to which the grantee has implemented key aspects of QFP. The grantee was assessed utilizing the listed criterion in OPA's QFP Clinical Assessment Checklist. The criterion identifies evidence of various aspects of quality services. The number of quality indicators identified as in place serve as a means for recognizing grantee achievements, as well as identifying areas not in place and therefore in need of improvement and/or technical assistance.

#### *Conclusion of Review and Evaluation Standards*

At the conclusion of the review, there was a Close-Out Presentation. Each review consultant reported on a few Areas of Success (AOS) and a few Areas of Improvement and Required Action (AOI) related to compliance and quality in their respective areas. Additionally, the reviewers also provide technical assistance to support improvements throughout the VPR.

This report is a more comprehensive compilation of the AOI and contains actions for addressing the AOI. If there was not sufficient evidence of compliance, the expectation is documented as being 'Not Met.' Each item 'Not Met' has a related 'Area of Improvement.' Each AOI is accompanied by a Required Action to aid the grantee in being compliant with Title X expectations. **Each AOI is accompanied by an "A" if it is an Administrative Area of Improvement (AOI); "C" if it is a Clinical Area of Improvement (AOI), and "F" if it is a Fiscal Area of Improvement (AOI).**

'Best Practice Suggestions' are recommendations that OPA encourages grantees to adopt to improve certain aspects of programming beyond meeting compliance expectations; however, grantees are not required to adopt these suggestions.

## Project Administration

### **Expectation 1:**

Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. (42 CFR § 59.5(a)(2))

#### **Review of Evidence Demonstrating Compliance (A):**

- TDH Family Planning Program Policy and Procedures (Revised May 2022), Voluntary Participation Policy effective April 1, 2022 revision date March 4, 2022
- General Consent for Health Services
- Chattanooga-Hamilton County Health Department Permission for Services
- Grant Contract Between the State of Tennessee and Hamilton County Health Department (7/1/22-6/30-27)
- Client Bill of Rights

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** Policies address this expectation. Training documentation shows staff complete annual training on this and other Title X expectations. The Manual addresses this expectation. FP staff are required to complete initial and annual training that includes this expectation. Subrecipient contracts require compliance with the Recipient's Administrative Manual. Recipient site visit reports show subrecipient and service sites are in compliance with this expectation. The forms used by TN FPP and subrecipient service sites include statements. The Client Bill of Rights Voluntary Participation section states clients may refuse any and all services without penalty. These Bill of Rights are posted near the intake desk at service sites.*

*The consent for services form states "I freely give consent for the receipt of health services provided by the staff of the Tennessee Department of Health." The form does not specifically state services are provided on a voluntary basis.*

*TDH Family Planning Program Policy and Procedures: References throughout the policies include a reference to the Program Requirements for Title X Funded Family Planning Projects. This document has been replaced by the Title X Program Handbook 2022.*

*Chattanooga-Hamilton County Health Department Permission for Services form does not state services are provided on a voluntary basis. The Chattanooga-Hamilton County Health Department subrecipient contract requires services to be provided without subjecting individuals to coercion to accept services or to employ or not to employ any particular methods of family planning.*

*Best Practice Suggestion: Remove the reference to Program Requirements for Title X Funded Family Planning Projects, Version 1.0 April 2014 included in the reference sections throughout the policies, and replace it with the Titles X Program Handbook 2022.*

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## **Expectation 2:**

Ensure that acceptance of services is solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the recipient. (Sections 1001 and 1007, PHS Act; 42 CFR § 59.5(a)(2))

### **Review of Evidence Demonstrating Compliance (A):**

- TDH Family Planning Program Policy and Procedures (Revised May 2022), Voluntary Participation Policy effective April 1, 2022 revision date March 4, 2022
- General Consent for Health Services
- Chattanooga-Hamilton County Health Department Permission for Services
- Client Bill of Rights
- Voluntary participation/non-coercion notice

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** The recipient has established written policies and procedures for compliance with this expectation. Documentation of training shows staff complete annual training on this expectation. The General Consent for Health Services form states "I do not have to use any other health department services in order to receive Family Planning services." The statement on the consent form used by the subrecipient reviewed directly addresses this expectation. Voluntary participation/non-coercion notices are posted near intake desks at clinic sites reviewed. A Title X Requirements Acknowledgement form is sent to staff via email annually. Staff are asked to read Title X requirements attached regarding non-discrimination, non-coercion, abortion prohibition, and confidentiality and sign the form for each expectation. The signed form should be returned to sender.*

*The state will resize and make more colorful the voluntary participation/non-coercion notice posted near the intake desk.*

*Best Practice Suggestion: Remove the following statement from the General Consent for Health Services form: "I do not have to use any other health department services in order to receive Family Planning services." Replace with "I understand that I have the right to refuse any and all treatment and medication."*

### **Review of Evidence Demonstrating Compliance (C):**

- Medical Records
- General consent forms

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

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**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *Medical Records in each subrecipient site consistently included signed general consents for family planning services.*

**Expectation 3:**

Ensure that staff are informed that any officer or employee of the United States, officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than \$1,000 or imprisoned for not more than one year, or both. (42 U.S.C. § 300a-8, as set out in 42 CFR § 59.5(a)(2) footnote 1)

**Review of Evidence Demonstrating Compliance (A):**

- TDH Family Planning Program Policy and Procedures (Revised May 2022), Voluntary Participation Policy effective April 1, 2022 revision date March 4, 2022
- Documentation of Annual training regarding Title X expectations

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TDH policy prohibits coercion to use any particular method or service. Training documentation shows staff completed annual training on this expectation. Site visit reports showed TN FPP monitors subrecipient and service sites for compliance with this expectation. Staff are asked to read Title X expectations regarding non-discrimination, non-coercion, abortion prohibition, and confidentiality and sign the form for each expectation. The signed form should be returned to sender via email.*

**Expectation 4:**

Provide services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status. (42 CFR § 59.5(a)(4))

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Cultural Competency
- TN Family Planning Program Policy and Procedures, Non-Discriminatory Services (eff 4/1/22; rev 3/22/22)
- TN Department of Health Non-Discrimination
- Chattanooga-Hamilton CHD Administrative Manual, Title VI Statement

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- TDH General Administration 2.0, Title VI Limited English Proficiency (LEP) Patient Services -- 2.16
- Client Bill of Rights
- Virtual service site tours

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The recipient has established policy and procedures regarding this expectation. Training documentation showed staff have completed annual Title VI Training. The Client Bill of Rights includes this non-discrimination statement. Title VI posters are on the walls throughout the service sites reviewed. A Title X Requirements Acknowledgement form is sent to staff via email annually. Staff are asked to read Title X expectations attached regarding non-discrimination, non-coercion, abortion prohibition, and confidentiality and sign the form for each expectation. The signed form should be returned to the sender.*

*Non-discrimination is addressed in the Hamilton County Government Employee Handbook. TDH General Administration establishes non-discrimination policies for all TDH programs that are receiving financial assistance. This policy is based on Title VI regs that do not include the categories in FP expectations. This policy addresses compliance regarding interpreter and translation services. It requires each region and metro CHD to develop a written LEP plan based on a needs assessment. Title VI posters are posted throughout the clinic.*

*Best Practices Suggestion: Revise the non-discriminatory services policy to include sexual orientation, gender identity, and sex characteristics.*

**NOTE: Expectation 5 was reviewed under Financial Accountability.**

### **Expectation 6:**

Provide services without the imposition of any durational residence expectation or an expectation that the client be referred by a physician. (42 CFR § 59.5(b)(5))

### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Durational Residency (eff 05/2022, rev 5/15/22)
- Chattanooga-Hamilton CHD Administrative Manual
- Staff Observations through role play (three sites reviewed)

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

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**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The policy prohibits the use of any residency expectation to access Title X services at any service site. Staff are trained on this expectation and TFPP staff monitor the services site for compliance. A review of site visit reports showed no findings related to this expectation.*

*Interviews with staff and observations of role play at the three sites reviewed revealed staff are aware of this expectation.*

**NOTE: Expectation 7 was reviewed under Provisions of High-Quality Family Planning Services.**

**NOTE: Expectation 8 was reviewed under Community, Education, Participation, and Engagement.**

**Expectation 9:**

Ensure that all information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipients must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client. (42 CFR § 59.10(a))

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Confidentiality (eff 4/1/22; rev 3/4/22)
- TDH Notice of Privacy Practices (rev 06/13)
- TDH website, Family Planning section
- General Consent for Health Services form
- Chattanooga-Hamilton County Health Department Individual Agreement to Preserve Confidentiality of Patient or Client Information and Records
- Chattanooga-Hamilton County Health Department Permission for Services
- Chattanooga-Hamilton County Health Department Administration Manual 2019
- TN Client Bill of Rights
- Observations of role play

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

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**Best Practices Suggestions & Additional Comments:** Staff complete initial and annual training on this policy. TDH Notice of Privacy Practices is offered to clients at their initial visit. TDH has implemented medical records system safeguards to ensure adequate privacy, security, and appropriate access to PII. The TDH FPP website informs viewers that clinical services are confidential. The training plan and training documentation were provided for review.

Role plays at the three sites reviewed showed intake staff emphasis that services are confidential.

A Title X Requirements Acknowledgement form is sent to staff via email annually. Staff are asked to read Title X requirements attached regarding non-discrimination, non-coercion, abortion prohibition, and confidentiality and sign the form for each expectation. The signed form should be returned to sender.

The TDH website, Family Planning section, states Confidential clinical services are offered in all 95 counties across the state at each of the local health departments. General Consent for Health Services does not specifically state services are confidential. Clients receive a copy of the HIPAA Notice of Privacy Practices. The Chattanooga-Hamilton County Health Department workforce are required to sign this confidentiality agreement. The form documents the individual has reviewed the policy. It further designates routine access for the individual. There are four access levels ranging from no access to full access based on the individuals' work positions. Chattanooga-Hamilton Permission for Services includes an acknowledgment of receipt of notice of privacy practices. Role play of staff at three sites reviewed showed staff have received training on confidentiality expectations and are in compliance with state and federal HIPAA and other confidentiality expectations.

**Review of Evidence Demonstrating Compliance (F):**

- Contracts with metropolitan health departments
- Administrative manual

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** N/A

**Expectation 10:**

Develop plans and strategies for implementing family planning services in ways that make services as accessible as possible for clients. (OPA Program Priority, as set out in PA-FPH-22-001 NOFO and the FY 2022 NOA Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Telehealth (eff 6/1/22, rev 5/10/22)

This expectation was **MET**.

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## **Areas of Improvement and Required Action (A): N/A**

### **Technical Assistance: N/A**

**Best Practices Suggestions & Additional Comments:** TDH wants to meet the people "where they are." TDH initiated telehealth services with Title X funding just prior to the beginning of the pandemic. A client calling for an appointment is offered a telehealth or in-person appointment. Telehealth appointments can originate from client's home, health service site, or other site with internet service. If internet service is not available, the appointment can be conducted using Facetime or an audio phone call. Telehealth staff emphasize the importance of confidentiality. Ninety-five percent of telehealth clients surveyed were very satisfied with their visit and would recommend telehealth to their friends and family. TDH hopes to expand these services when funding and staffing permits. Hamilton County Health Department began offering telehealth services during COVID. Pre-pandemic, some clinics offered extended hours. Hamilton County plans to resume services during extended hours post-pandemic. Pre-pandemic, TDH began a process to assess service sites to determine their accessibility to vulnerable population. TDH surveyed 124 sites for their accessibility to teen, male, and LGBTQ+ persons. Plans were paused due to the pandemic. Based on survey results, TDH plans to increase the accessibility of services for a more diverse population. The percent of family planning users who are male is low (3%). TFPP staff along with Family Planning Administrators in the regions and metro are working to develop strategies to serve more males.

Pre-pandemic, the TDH began a process to assess service sites to determine their accessibility to vulnerable populations. The first year TDH surveyed 124 sites for their accessibility to teen, male, and LGBTQ+ persons. Plans were paused due to the pandemic. Survey results were provided for review. Based on survey results, TDH will increase the accessibility of services for a more diverse population.

Chattanooga-Hamilton CHD: Extended clinic hours, telehealth, med refill pickup dates without receiving services (pharmacy-like), FP ANPs are on a rotating schedule working in STD clinics to interact with male clinics and offer to fast track family planning services. The arrangement keeps the lines of communication open between STD clinic staff and FP staff. The site is trying to get word out that the HD provides family planning services for males. Pre-pandemic Chattanooga-Hamilton CHD offered services during extended hours. Plan to resume this schedule when feasible.

Recipient understands the need to increase the number of males receiving FP services. Are exploring a variety of options, particularly warm handoff from STD.

### **Expectation 11:**

Identify and execute strategies for delivering services that are responsive to the diverse needs of the clients and communities served. (OPA Program Priority, as set out in PA-FPH-22-001 NOFO and the FY 2022 NOA Special Terms and Expectations)

### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Telehealth (eff 6/1/22, rev 5/10/22)
- TN Family Planning Program Policy and Procedures, Facilities and Accessibility of Services (eff 11/6/2002; rev 12/6/2019)

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- FY 22 Competitive Application
- General Administration 2.0, Title VI Limited English Proficiency (LEP) Patient Services 2.16
- Chattanooga-Hamilton County Health Department Administrative Manual

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The TN Department of Health and Chattanooga-Hamilton County Health Department provide telehealth services as an option for FP service delivery. Clients calling for an appointment are offered an in-person or telehealth appointment. Clients needing language assistance have presented a problem with telehealth appointments. The ANP uses Doxy.me or facetime to conduct these appointments. She has not been able to link in an interpreter. She has tried using the language line to complete the appointment but has not been satisfied with that option since she cannot see the patient and gauge her reactions. TDH should identify a communication method that will allow interpreters to participate in face-to-face meetings to provide interpreter services. TDH contracts for interpreter services at all clinic sites. Some sites have an interpreter on site (Spanish/English). Each region/metro is required to develop a written LEP plan to provide interpreter services. Translation services are provided through the Tennessee Foreign Language Institute. Virtual tours showed notices of availability of interpreter services in a variety of languages posted near the intake desk at service sites reviewed. Other notices and posters are posted in English and Spanish. Hamilton County has a Kurdish population and their brochures have been translated into Arabic.*

*TDH implemented the outreach initiative, Neonatal Abstinence Syndrome (NAS) Reduction Effort Through Expanded Access to Family Planning Services, in 2015. Family Planning staff provide education about NAS prevention and available Family Planning services. The opioid epidemic and COVID-19 pandemic resulted in an uptick in the number of opioid overdoses. All Family Planning clients are screened for substance abuse. TFPP works collaboratively with the Tennessee Department of Mental Health and Substance Abuse to provide seamless continuity of care.*

*The TN Accessible Transportation and Mobility Act of 2020 created a new office within the Tennessee Department of Transportation. The purpose is to provide resources and expertise for expanding and improving accessible transportation and mobility across the state. Efforts to address transportation barriers for clients include: outside of health department service locations, free bus passes, partnering with A Step Ahead program to provide transportation to women through Uber and Lyft services.*

*TDH partners with The Rape Prevention and Education program that focuses on preventing sexual violence perpetration and victimization.*

*Best Practice Suggestion: TDH FPP staff should explore options for telehealth service delivery for LEP clients needing interpreter services.*

## **Expectation 12:**

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Provide notice to OPA in the Title X Clinic Locator Database (<https://opa-fpclinicdb.hhs.gov/>) of any deletions, additions, or changes to the name, location, street address and email, services provided on-site, and contact information for Title X recipients and service sites. Changes must be entered into the database within 30 days from the official OPA/GAM prior approval expectation for changes in project scope, including clinic closures. (PA-FPH-22-001 NOFO and the FY 2022 Notice of Award Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (A):**

- Interview with grant recipient staff

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** The TFPP Project Director has assigned the responsibility for maintaining the clinic locator database to a staff member. This staff member monitors local service sites and subrecipient agencies and updates the database as needed.*

**Expectation 13:**

If enrolled in the 340B Program, comply with all 340B Program expectations. 340B Program expectations are available at <https://www.hrsa.gov/opa/program-expectations/index.html>. (FY 2022 Notice of Award Special Terms and expectations)

**Review of Evidence Demonstrating Compliance (F):**

- Inventory check
- Staff interviews

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** N/A*

**Expectation 14:**

May copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a federal award. The federal government reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so. The awardee is subject to applicable regulations governing patents and inventions, including government- wide regulations issued by the Department of Commerce at 37 CFR part 401. The federal government has the right to: obtain, reproduce, publish, or otherwise use

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the data produced under this award; and authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

**Review of Evidence Demonstrating Compliance (A):**

- Interview with Project Director

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 15:**

Acknowledge Federal funding when issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter "statements")-- describing the projects or programs funded in whole or in part with HHS federal funds, the recipient must clearly state the percentage and dollar amount of the total costs of the program or project funded with federal money and the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

**Review of Evidence Demonstrating Compliance (A):**

- No written policies and procedures
- Outreach and educational materials

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** *The Recipient does not have any written policies and procedures for compliance with this federal expectation. Federal funding was acknowledged on the Title X Family Planning brochure developed and printed by the Tennessee Family Planning Program, but the acknowledgement does not match either of the acknowledgements included in this expectation. The acknowledgement on the brochure is as follows: "This publication was made possible by grant #FPHPA040651 from the US Department of Health and Human Services. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the US Department of Health and Human Services."*

*Interview with the Project Director revealed this is the only brochure developed by the project. The acknowledgement does include some of the wording included in one of the acknowledgements. Reviewer recommended the Project Director submit the acknowledgement currently on the Family Planning Brochure to their federal project officer for approval.*

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*The Family Planning brochure has a statement acknowledging federal funding, but the statement is not required in this expectation. None of the other outreach material or brochures were developed and printed using Title X funding.*

*The Family Planning brochure acknowledges grant support but does not use the language required. Subrecipient contracts do not include this expectation.*

*Best Practice Suggestion: Develop written policies and procedures acknowledging federal funding when issuing statements, press releases, publications, requests for proposals, bid solicitations, and other documents, and include this expectation in subrecipient contracts. Submit acknowledgment currently used on the Family Planning brochure to the OASH federal project officer and the OASH grants management specialist for approval.*

## Provision of High-Quality Family Planning Services

### Expectation 1:

Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. (Section 1001, PHS Act; 42 CFR § 59.5(a)(1))

Title X service sites are expected to provide most, if not all, of acceptable and effective medically approved family planning methods and services on site and must detail the referral process for family planning methods and services that are unavailable on-site.

### **Review of Evidence Demonstrating Compliance (C):**

- Family Planning Clinical Guidelines
- Client education/counseling protocol
- Family Planning Public Health Nursing Protocols
- Medical records review
- Documentation of staff training
- Interview with Training Manager

This expectation was **MET**.

### **Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** The reviewer recommended that basic infertility services, a core, and required Title X family planning service for men and women, alike, are offered on-site to clients instead of through the current referral process. These services, recommended by QFP, ACOG, and the American Urological Society are defined in QFP, page 14. RHNTC has several succinct resources for the offering of these services which are within APN's scope of training and practice. The reviewer also recommended that the Family Planning Clinical Guidelines, last updated in 2021, be reviewed annually.

**Best Practices Suggestions & Additional Comments:** *Direct observation of client care substantiated that client were made aware of all FDA-approved contraceptives and their availability within the program. The Family Planning Program has a high usage of LARCs, and educational materials regarding NFP and liberally dispenses latex and non-latex condoms. Both clinics consistently offer same day starts for contraceptives. The Polk-Benton APN does not insert LARCs (a referral process is in place for these methods) and is willing to have updated training for these methods. The Clinical Manager could consider offering this APN supervised insertion opportunities at another clinic in order to enable her independent practice. Expedited partner treatment for STIs is readily available as are referrals for PrEP, after counseling regarding this medication. Reproductive life planning discussions and medical histories were consistently documented in all pregnancy testing records. Only one of the records included documentation that clients with positive tests were assessed for social support. Otherwise, all documentation was in*

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accordance with QFP principles. All staff had evidence of QFP training as it relates to pregnancy counseling.

### **Expectation 2:**

Ensure that Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a prescription to the client for their method of choice or referrals to another provider, as requested. (42 CFR § 59.5(a)(1))

#### **Review of Evidence Demonstrating Compliance (C):**

- Clinic Protocol
- Referral list
- Medical records review

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** Clinics provide all family planning methods and services, including referrals for sterilization and LARCs (provided on a sliding fee scale) if they are not available on-site. TFPP has an agreement with the University of Nevada, Reno, to perform vasectomies on clients that they have counseled regarding this contraceptive option, and those clients are charged on a sliding fee scale. The Recipient offers a broad range of contraceptives including several types of oral contraceptives, two types of IUDs and emergency contraception, and Depo Provera( IM and SQ). They offer a full year's supply of oral contraceptives if clinically not contraindicated, at the time of method initiation.*

### **Expectation 3:**

Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed. (42 CFR § 59.5(a)(3))

#### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Cultural Competency (rev 3/10/22; Eff date 4/1/22)
- Client Dignity Protocol
- Chattanooga-Hamilton CHD Administrative Manual, Interpretation Services
- Chattanooga-Hamilton CHD Administrative Manual, Interpreters Provided by Clients
- Virtual clinic tour
- Training documentation

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

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**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TN has a policy of non-discrimination in employment. The virtual tour showed non-discrimination in employment posters and vacancy announcements (at one site) on the walls in the two sites reviewed. TDH staff complete cultural diversity training annually. Client satisfaction surveys assess the degree to which they feel the staff are sensitive to and able to deal effectively with the client population. Service sites conduct patient satisfaction surveys for a period of at least five working days during the calendar year. TDH staff collaborates with Health Councils composed of diverse stakeholders who look at data, identify disparities, and select priority areas to work on. I&E and outreach Family Planning materials are in English and Spanish. Limited material has been translated into Arabic. Interpreter services are available statewide through a language line. Hamilton County has Spanish-speaking interpreters available onsite.*

*The Chattanooga-Hamilton CHD Administrative Manual states that clients choosing to use their own interpreter must sign a waiver stating they were informed of an interpreter free of charge and of the risk of using their own interpreter but choose to use their interpreter. Signage in the building is in Spanish and English. FP brochures are in Spanish, English, and Arabic. Notice of availability of interpreter service is posted on the wall near the intake desk.*

**Review of Evidence Demonstrating Compliance (C):**

- Recipient and subrecipient agencies have written policies and procedures addressing this expectation
- Copies of Materials translated into other languages that are available to patients
- LGBTQ Assessments
- Translation services policy
- Client education/counseling materials, etc.
- Medical record review
- Staff trainings
- Policies, procedures, and Protocols

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *Direct client/provider observations reflected client-centered care that was also trauma-informed. The Recipient has conducted LGBTQ+ assessments with an inclusive tool to evaluate quality services to these clients. Trauma-informed education was consistently documented in the medical records reviewed. The Hamilton clinic has Spanish interpreters (22% of the clients are Hispanic) on-site and both clinics utilize language lines. The Hamilton clinic has a gender-neutral bathroom identified during the tour of the facility.*

**Expectation 4:**

Provide services in a manner that protects the dignity of the individual. (42 CFR § 59.5(a)(3))

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**Review of Evidence Demonstrating Compliance (C):**

- TNDOH Administrative Manual
- Client Dignity protocol
- Observation of client education

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP has a policy dated March 2022 describing the program's process for ensuring that services are provided in a manner that protects clients' dignity. Direct observation of client care role plays in each subrecipient site exemplified this standard of care.*

**Expectation 5:**

Provide services in a manner that ensures equitable and quality service delivery consistent with nationally recognized standards of care. (42 CFR § 59.5(a)(3))

**Review of Evidence Demonstrating Compliance (C):**

- Documentation of staff training
- Clinic Protocol
- Family Planning Clinical Guidelines, 2021
- Observation of client education; medical record/chart review

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP participates in the TDH Division of Family Health and Wellness health equity planning and implementation task force. This collaboration ensures that family planning policies reflect and value the potential of every client.*

**Expectation 6:**

Provide quality family planning services that are consistent with the Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the U.S. Office of Population Affairs (QFP) and other relevant nationally recognized standards of care. (OPA Program Priority, PA-FPH-22-001 NOFO, and the FY 2022 NOA Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (C):**

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- Documentation of staff training
- Clinic Protocol
- Client education
- Counseling Protocol
- FPAR data
- Observation of Client interactions

This expectation was **NOT MET**.

**Areas of Improvement and Required Action (C):** The number of male clients seen in the TFPP, less than 3% of the client total in 2021, is far below the national average. The Hamilton program had no male client medical records available for the review. The TFPP program needs to achieve health equity for the male population, particularly those of low income, by increasing outreach to males and recruiting males into the program. The TFPP must develop a protocol specific to males, including the family planning and related preventative health services recommendations in QFP's checklist for male services (page 23).

**Technical Assistance:** The reviewer discussed strategies with TFPP staff, including collaboration with STD programs to partner in addressing those needs of male patients and promoting services that will safeguard the reproductive health of both men and women. Marketing efforts could include distributing male-friendly brochures in posters in establishments, such as bars and gyms, where males congregate. Opportunities can be optimized to provide men with reproductive health care by converting a standalone visit (e.g., an STD screening request) to a more comprehensive family planning visit that also addresses issues related to unintended pregnancy prevention including sexual risks, contraception, and reproductive life planning. This approach is especially important for men who otherwise might not receive these services.

**Best Practices Suggestions & Additional Comments:** *Midlevel nurse practitioners identified their comfort in seeing male clients. The TFPP has well-designed visual materials (e.g., posters and brochures) intended for a male audience. The Family Planning National Training Center has developed a checklist for family planning and related health services for men based on CDC, QFP, and OPA recommendations. Increasing services to the male population will facilitate preconception health for both men and women. The FPP needs to maximize these resources, identify current barriers to reaching males and create a plan to increase services to this population.*

### **Expectation 7:**

Advance health equity through the delivery of Title X services. Health equity is when all persons have the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances. (OPA Program Priority, PA-FPH-22-001 NOFO, the FY 2022 NOA Special Terms and Expectations, and 42 CFR § 59.2)

### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, non-discriminatory Services, Client Dignity
- FP Training documentation
- Observation during Role Play

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This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *Non-discriminatory services, client dignity, confidentiality, and other policies assure clients have access to reproductive health services. Training documentation showed that staff have completed annual non-discrimination, confidentiality, cultural diversity, and other required training. Staff have interpreter services available statewide through a language line. During role play observation, intake staff showed they are sensitive to the needs of clients and emphasize confidentiality. The clinic site reviewed is handicap accessible. Both sites have a gender-neutral restrooms.*

*Documentation of training provided for staff in the metro and region were reviewed.*

**Review of Evidence Demonstrating Compliance (C):**

- Documentation of staff training
- Client education/counseling protocol
- Observations and interviews
- Referrals policy or system/process

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The recipient's work plan identifies two specific goals in advancing health equity. TFPP, together with TDH, are working with a Health Equity consultant to prepare a health equity disparity impact statement.*

**Expectation 8:**

Improve and expand accessibility of services for all clients, especially low-income clients by providing client-centered services that are available when and where clients need them and can most effectively access them. (OPA Program Priority, PA-FPH-22-001 NOFO, and the FY 2022 NOA Special Terms and Expectations).

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Telehealth (eff 6/1/22, rev 5/10/22)
- TN Family Planning Program Policy and Procedures, Facilities and Accessibility of Services (eff 11/6/2002; rev 12/6/2019)
- Chattanooga-Hamilton County Health Department Administrative Policies
- Virtual tour of clinic sites

This expectation was **MET**.

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**Areas of Improvement and Required Action (A): N/A**

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *Surveys of TDH TFPP telehealth services have shown that 95% of the clients are satisfied with their services and would recommend telehealth to friends and family. TFPP plans to expand services as funding and staffing are available. Hamilton County Health Department offered extended hours pre-pandemic and initiated telehealth during the pandemic. The Health Department plans to resume extended hours schedule and expand telehealth services and offer quick med pickup (similar to pharmacies). Hamilton County plans outreach to a small Kurdish population in the county. TFPP staff have been working with the Epidemiologist to establish outreach potential. For example, mapping the counties serving less than 21% of Females aged 19-44 who are potentially eligible for Title X FP services.*

*Chattanooga-Hamilton County Health Department: Pre-pandemic offered extended hours so that clients could access services after work. During the pandemic, offered telehealth service and drive-through meds pickup. When fully staffed and open, plan to resume and expand telehealth services and offer quick med pickup (similar to pharmacies). The main clinic reviewed has free parking in a garage, automatic door opening, and elevators. Handicap-accessible, gender-neutral restrooms are available. The building is large and well laid out to accommodate individuals with mobility issues. Maps are posted on the walls to direct clients to available services, including family planning. Spanish-speaking interpreters are onsite, and a language line is available for other languages. FP APNs work in an STD clinic periodically to provide FP information and intake for FP services to male clients. The clinic serves a racially diverse population. There has been an increase in outreach to the Kurdish population in the county.*

*Polk County Health Department is attractive and well laid out. A gender-neutral restroom is available. The entrance door is not automatic, but staff indicated there are plans to update it. Polk County is a small, rural county. The Benton clinic served only 39 patients and no males.*

**Review of Evidence Demonstrating Compliance (C):**

- Client education/counseling materials
- Telehealth protocol
- Transportation access (Client mobility)
- Clinic layout
- Needs assessment
- Patient observation
- Interpretation services

This expectation was **MET**.

**Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The Telehealth program greatly enhances clients' access to services through the offering of flexible hours and obviating the need for transportation.*

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### **Expectation 9:**

Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination. If requested to provide such information and counseling, projects must provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. (42 CFR § 59.5(a)(5), Title X appropriations)

#### **Review of Evidence Demonstrating Compliance (C):**

- Documentation of staff training
- Pregnancy Testing and Counseling Protocol
- Referral list
- Medical Records review
- APN staff interviews
- Pregnancy Testing and Counseling Protocol
- Referral lists
- Medical Records review
- Observation of Pregnancy Counseling visit
- Staff interview

This expectation was **MET**.

#### **Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** The reviewer strongly recommended the addition of pregnancy testing to the family planning brochure's list of services.

**Best Practices Suggestions & Additional Comments:** *Non-directive pregnancy counseling is offered by nurse practitioners. No referrals for abortion are made. Prenatal precautions, according to the protocol, are documented in the medical records reviewed. The protocol for pregnancy counseling conforms with federal expectations for this service.*

### **Expectation 10:**

Provide that family planning medical services will be performed under the direction of a clinical services provider (CSP), with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning. CSPs include physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user (male and female) physical assessments recommended for contraceptive, related preventive health, and basic infertility care. (42 CFR § 59.5(b)(6) and 42 CFR § 59.2)

#### **Review of Evidence Demonstrating Compliance (C):**

- CVs (Grantee, Hamilton, and Polk-Benton) Medical Directors
- Interviews with three Medical Directors and APNs

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- Description of Position

This expectation was **MET**.

**Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** The reviewer recommended that the recipient's medical director reach out to the program's regional directors on a regular basis (e.g., quarterly newsletter) apprising them of any news or update regarding the TFPP.

**Best Practices Suggestions & Additional Comments:** *TFPP's Medical Director was engaged with the review process during each day of this program review. She has reviewed and signed TFPP protocols and policies. She has many years of experience in family planning and women's health and has attended several annual FP updates, contraceptive technology update conferences, and the past two virtual national reproductive health conferences hosted by the national clinical training center. Hamilton's medical director job description stated that the physician serves as the clinical supervisor/collaborator with the advanced practice nurses which includes monthly chart reviews, reviewing and approving protocols, and clinical guidelines used in various clinics. This subrecipient has an APN/MD Preceptor Agreement stipulating that family planning services are under the supervision of the physician preceptor. The newly appointed Medical Director will be attending an upcoming reproductive health care conference. An OB/GYN physician is available to Hamilton APNs for consultation Pol-Benton's medical director is a board-certified family medicine physician with recent continuing education in reproductive health. All medical directors confirmed that they are familiar with QFP.*

**Expectation 11:**

Ensure that non-clinical counseling services (such as contraceptive counseling, nondirective options counseling, reproductive health goals, etc.) is provided by any adequately trained staff member who is involved in providing family planning services to Title X clients, this may include CSPs and non-CSPs (e.g., health educators). (2021 Final Rule FAQs)

An “adequately trained staff member” has attended and participated in required orientation, courses, curriculums, and/or teaching/mentoring experiences, maintains appropriate competencies, and is knowledgeable and proficient in providing non-clinical counseling services.

**Review of Evidence Demonstrating Compliance (C):**

- Documentation of staff training/education
- Observation of Client Education session and/or staff interview
- Medical record review

This expectation was **MET**.

**Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** N/A

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***Best Practices Suggestions & Additional Comments:*** Not all TFPP staff have completed training in QFP. Completing this training will familiarize these members with the principles designed to optimize care. Direct observation of non-clinical counseling reflected the staff member's ability to appropriately follow up on non-verbal cues from the client. The RLP was consistently discussed in all observed client/provider interactions, as well as documented in medical records reviewed.

## Adolescent Services

### **Expectation 1:**

Apply all expectations listed under “Provision of Quality Family Planning Services” when providing services to adolescent clients.

#### **Review of Evidence Demonstrating Compliance (C):**

- Observation and staff interview
- Medical records review
- Adolescent Clinical Protocol

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** TFP's adolescent population, at 19% is higher than the national average.

### **Expectation 2:**

Provide adolescent-friendly health services, which are services that are accessible, acceptable, equitable, appropriate and effective for adolescents. (42 CFR § 59.2)

#### **Review of Evidence Demonstrating Compliance (C):**

- Medical records review
- Client education/counseling materials
- Observations and staff interviews
- Inspection of Title X subrecipient sites
- Schedule of site hours

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** The TFP Adolescent Service policy identifies QFP's five key principles to ensure quality counseling and education.

### **Expectation 3:**

To the extent practical, Title X projects shall encourage family participation. However, Title X projects may not require consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and/or received Title X family planning services. (Section 1001, PHS Act; 42 CFR § 59.10(b))

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**Review of Evidence Demonstrating Compliance (A):**

- FP PHN Protocols, Adolescent Services
- TN Family Planning Program Policy and Procedures, Confidentiality
- Training documentation
- Client Bill of Rights
- Training Plan
- TN Family Planning Program Policy and Procedures, Compliance with Legislative Mandates (eff 4/1/22; rev 3/22)
- Role plays

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP has written an Adolescent Services policy requiring counseling regarding encouraging family participation in the decision of minors to seek family planning services. Parental consent is not required for minors to receive services. Site visit reports show subrecipients and services sites are assessed for compliance with this expectation. The training plan includes annual training on this expectation and training documentation shows staff completed this training. The Client Bill of Rights posted near intake desks in clinics assures clients that their health records are private, and services will be provided in ways that ensure privacy and safety. Intake staff during role play assured clients their insurance would not be billed, and the health department would not mail anything to their homes if they were seeking confidential services.*

**Review of Evidence Demonstrating Compliance (C):**

- Observation and staff interviews
- Adolescent counseling and education protocol

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *Role play scenarios in each Hamilton and Polk-County clinic demonstrated that staff confirms with adolescent patients that project staff will not notify a parent or guardian before or after a minor has requested and/or received Title X family planning services.*

**Expectation 4:**

Ensure that all applicants for Title X funds certify that they encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on how to

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resist attempts to coerce minors into engaging in sexual activities. (Legislative Mandate set out in the Annual HHS Appropriations Act)

**Review of Evidence Demonstrating Compliance (A):**

- FP PHN Protocols, Adolescent Services
- Training Plan and documentation of training
- 2022 Administrative Manual Tennessee Family Planning Program

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** TDH FPP policy requires providers to counsel on ways to resist sexual coercion and on encouraging family involvement at the initial reproductive health encounter and at least annually. Parental consent is NOT required in order to receive services. Information will not be shared without the minor's consent. Minors presenting with a parent or guardian must be offered the opportunity to receive counseling and/or examination separately from the parent(s)/guardian(s). The Administrative Manual states adolescents may consent to family planning services without the consent of a parent. The Adolescent Consents and Counseling section of the manual further states that adolescents must be counseled on how to resist being coerced into engaging in sexual activities and encourage the minor to involve their family in their decision to seek family planning services. Site visit reports reviewed found service sites were in compliance with these expectations.*

**Review of Evidence Demonstrating Compliance (C):**

- Adolescent Services Protocol
- Observations and staff interviews

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** The Adolescent Services protocol clearly stipulates legislative expectation mandates and the review of medical records consistently documented age-appropriate counseling in this regard. The protocol offers an example of a well-written script encouraging minors' inclusion in family participation. All chart reviews, male and female alike, had documented adolescent counseling. Medical records reviewed for both the Hamilton and Polk-Benton sites had consistent and complete adolescent counseling documented. Role plays with adolescent clients at each site, similarly included this counseling, including that with a male client.*

**Expectation 5:**

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No Title X services provider shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest. (Legislative Mandate set out in the Annual HHS Appropriations Act)

**Review of Evidence Demonstrating Compliance (A):**

- 2022 Administrative Manual Tennessee Family Planning Program, Mandatory Reporting Requirement
- TN Family Planning Program Policy and Procedures, Confidentiality
- TN Family Planning Program Policy and Procedures, Compliance with Legislative Mandates
- FP PHN Protocols, Adolescent Services
- Training Plan and documentation of training

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** TDH FPP policy requires staff to report suspected abuse in compliance with state reporting laws. The training plan requires training on this expectation to be completed annually. Documentation showed staff training is up to date. The training is provided by the Tennessee Department of Children's Services (Mandated Child Abuse Reporting Training). A Title X: Mandatory Reporting Acknowledgement form is sent via email to staff annually. Staff may use the form to report training completed and upload certificates of completion.*

**Review of Evidence Demonstrating Compliance (C):**

- Child Abuse Protocol
- Adolescent Services Policy

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** The Adolescent Services Policy for TFPP stipulates that the TNDH policy "Reporting Child Abuse" must be followed to report suspected abuse. This policy comprehensively addresses the legislative reporting mandate.*

## Referral for Social and Medical Services

### **Expectation 1:**

Provide referrals for medical services related to family planning and to other medical facilities when medically indicated thereby provide for the effective usage of contraceptive devices and practices. (42 CFR § 59.5(b)(1))

#### **Review of Evidence Demonstrating Compliance (C):**

- Referral Protocol
- Referral Lists
- Medical records review

This expectation was **MET**.

#### **Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** The reviewer recommended that out-of-state abortion referral resources are available at the Hamilton site to clients who request this information for an unintended pregnancy, (insofar as this procedure will no longer be available in Tennessee).

**Best Practices Suggestions & Additional Comments:** Subrecipient sites have effective processes for referrals to medical, mental health, and social service agencies. TDFP has established and maintains collaborative relationships with Community Health Centers, and the Rural Health Services Consortium, among others, and an agreement with A STEP AHEAD program allows Title X clients free LARCs and insertions, and transportation or fuel vouchers to facilitate appointments. Documentation was seen in the medical record when referrals were made based on a documented specific condition/issue. The Hamilton subrecipient site has a current (May 2022) and comprehensive list of abortion providers in nearby states who provide abortion to clients who request this information for an unintended pregnancy, (insofar as this procedure will no longer be available in Tennessee, effective August 25, 2022 due to Tennessee's Human Life Protection Act banning all abortions).

### **Expectation 2:**

Provide referrals for social services related to family planning and to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance. (42 CFR § 59.5(b)(2))

#### **Review of Evidence Demonstrating Compliance (C):**

- Recipient needs assessment
- Clinical protocol

This expectation was **MET**.

#### **Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** N/A

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**Best Practices Suggestions & Additional Comments:** *The recipient needs assessment has documented the social service and medical needs of the community to be served and identified relevant social and medical services available to help meet those needs. Eighteen Tennessee counties have A Step Ahead Program which provides free transportation to facilitate clinic attendance and referral visits.*

### **Expectation 3:**

Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care. (42 CFR § 59.5(b)(8))

### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Availability of Social Services (eff 4/1/22; rev 3/21/22); Availability and Use of Referrals (eff 4/1/22; rev 3/22/22)
- MOU TDH and Christ Community Health Center, Inc.
- FY22 Competitive Application
- MOU template

This expectation was **MET**.

### **Areas of Improvement and Required Action (A):** N/A

### **Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP service sites are required to have a process to refer clients for social and medical services. Polk County HD does not have formal agreements for these services but does have a resource list. Resource lists were available in the waiting rooms of both clinic sites reviewed. Regional/Metro Family Planning Administrators (FPA) along with healthcare experts and clinic staff are responsible for vetting providers and referral resources. Referral resources are required to be updated annually.*

*The MOU template addresses referrals between agencies and clarifies that it is not an exclusive arrangement.*

*Chattanooga-Hamilton CHD refers clients to CEMPA: FOR PrEP. Chattanooga-Hamilton CHD referral/resources list includes Erlanger FQHC and other CHCs, private physicians, etc.*

*Polk County Health Department refers to Centennial Medical Center in Nashville for patients desiring tubal ligations and to private providers for patients desiring sterilizations. Both referral resources charge Title X referred clients on a sliding fee scale.*

*Both sites visited have a resource list for providers in the area.*

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#### **Expectation 4:**

Ensure service sites and subrecipients have strong links to other community providers to ensure that clients have access to primary care. If a client does not have another source of primary care, priority should be given to providing related reproductive health services or providing referrals, as needed. Screening services such as, medical history; cervical cytology; clinical breast examination; mammography; and pelvic and genital examination should be provided for clients without a primary care provider, where applicable, and consistent with nationally recognized standards of care. In addition, appropriate follow-up, if needed, should be provided while linking the client to a primary care provider. (QFP, p.20, [https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014\\_1.pdf](https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf) )

#### **Review of Evidence Demonstrating Compliance (C):**

- Referral Protocol
- Medical records review
- Staff interviews

This expectation was **MET**.

#### **Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** Medical records had consistent documentation regarding clients' primary care provider(s). In cases where there were none, referrals were documented.

**Best Practices Suggestions & Additional Comments:** *If a client does not have another source of primary care, screening services such as medical history, cervical cytology, clinical breast examinations, and pelvic and genital examinations are provided for clients, where applicable, consistent with nationally recognized standards of care. TFPP has an MOU with specialty service providers to follow up on abnormal Pap smears and breast exams. TFPP maintains collaborative agreements with various referral agencies, including emergency care, HIV/AIDS care, and treatment providers, infertility specialists, primary care, and chronic care management providers.*



## Financial Accountability

### **Expectation 1:**

Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge. Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902 (2). "Low-income family" also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. (Section 1006(c)(1), PHS Act; 42 CFR § 59.5(a)(7) and 42 CFR § 59.2)

#### **Review of Evidence Demonstrating Compliance (F):**

- Patient chart reviews
- Schedule of discounts
- Fee schedule
- Review capture of patient income declaration in the EHR
- Financial policies review
- Administrative manuals

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

### **Expectation 2:**

Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources. (Section 1006(c)(1), PHS Act; 42 CFR § 59.5(a)(7) and 42 CFR § 59.2)

#### **Review of Evidence Demonstrating Compliance (F):**

- 5 charts were reviewed for each site (minors seeking confidential services included in the samples)
- Role play
- Administrative manual

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

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***Best Practices Suggestions & Additional Comments: N/A***

**Expectation 3:**

Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services. (42 CFR § 59.5(a)(8))

The schedule of discounts should be updated annually in accordance with the FPL.

**Review of Evidence Demonstrating Compliance (F):**

- Chart Reviews
- Schedule of discounts
- Fee schedule
- Interview on the setting of charges
- Review patient income declaration forms
- Role play, policy review
- Determination of fees framework

This expectation was **MET**.

**Areas of Improvement and Required Action (F): N/A**

**Technical Assistance: N/A**

***Best Practices Suggestions & Additional Comments: N/A***

**Expectation 4:**

Ensure that family income is assessed before determining whether copayments or additional fees are charged. (42 CFR § 59.5(a)(8))

**Review of Evidence Demonstrating Compliance (F):**

- Patient chart review
- Policy review
- Role play
- Patient income declarations
- Administrative manual
- Financial policies
- Interviews

This expectation was **MET**.

**Areas of Improvement and Required Action (F): N/A**

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**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 5:**

Ensure that, with regard to insured clients, clients whose family income is at or below 250 percent of the FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. (42 CFR § 59.5(a)(8))

**Review of Evidence Demonstrating Compliance (F):**

- Patient chart review
- Financial policy review
- Role play
- Staff interviews
- Administrative manual

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 6:**

Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income. (42 CFR § 59.5(a)(9))

**Review of Evidence Demonstrating Compliance (F):**

- Patient chart reviews
- Financial policies review
- Patient intake and disclosure forms
- Role play
- Administrative manual
- Patient income declaration forms
- Patient billing records

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

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**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 7:**

Take all reasonable efforts to obtain the third-party payment without application of any discounts, if a third party (including a Government agency) is authorized or legally obligated to pay for services. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required. (42 CFR § 59.5(a)(10))

**Review of Evidence Demonstrating Compliance (F):**

- Patient chart review
- Role play
- Financial policies review
- Administrative manuals
- Staff interviews
- Patient billing records

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 8:**

Provide that all services purchased for project participants will be authorized by the project director or their designee on the project staff. (42 CFR § 59.5(b)(7))

**Review of Evidence Demonstrating Compliance (F):**

- Fiscal policies review
- Staff interviews
- Administrative manual
- Purchasing policies

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

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### **Expectation 9:**

Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary. (42 CFR § 59.5(b)(9))

#### **Review of Evidence Demonstrating Compliance (F):**

- Financial policies review
- Staff interviews
- Contract review with the metropolitan health departments
- Internal site visit audits

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

### **Expectation 10:**

Maintain financial policies and procedures that are in compliance with 45 CFR Part 75, Uniform Administrative expectations, Cost Principles, and Audit expectations for HHS Awards. (PA-FPH-22-001 NOFO and Notice of Award Terms and Expectations)

#### **Review of Evidence Demonstrating Compliance (F):**

- Financial policies review
- Staff interviews
- Administrative manual

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

### **Expectation 11:**

Ensure that no mobile health unit(s) or other vehicle(s), even if proposed in the application for the Title X award, is purchased with award funds without prior written approval from the grants management officer. Requests for approval of such purchases must include a justification with a cost-benefit analysis comparing both purchase and lease options. Such requests must be submitted

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as a Budget Revision Amendment in Grant Solutions. (Notice of Award Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (F):**

- NOA Review
- Staff interviews
- Fiscal policies
- Administrative manual

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 12:**

Include financial support from sources other than Title X as no grant may be made for an amount equal to 100 percent of the project's estimated costs. Although projects are expected to identify additional sources of funding and not solely rely on Title X funds, there is no specific amount of level of financial match expectation for this program. (42 CFR § 59.7(c), PA-FPH-22-001 NOFO, Notice of Award Special Terms and Expectations)

\*Exception for territories and freely associated states as noted in the NOFO

**Review of Evidence Demonstrating Compliance (F):**

- NOA Review
- Budget review
- FFR reports
- Financial statements

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 13:**

Ensure that program income (fees, premiums, third-party reimbursements which the project may reasonably expect to receive), as well as State, local and other operational funding, will be used to finance the non-federal share of the scope of project as defined in the approved grant application and reflected in the approved budget. Program income and the level projected in the approved

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budget will be used to further program objectives. Program Income may be used to meet the cost sharing or matching expectation of the Federal award. The amount of the Federal award stays the same. Program Income in excess of any amounts specified must be added to the Federal funds awarded. They must be used for the purposes and conditions of this award for the duration of the Project period. 45 C.F.R. § 75.307 (e), Notice of Award Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (F):**

- Policy & procedure review FFR
- Budgets
- Cost allocation methodology
- NOA review
- Administrative manual
- Staff interviews
- Financial policies

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 14:**

Ensure that Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office. (Annual Appropriations Bill)

**Review of Evidence Demonstrating Compliance (F):**

- Financial policies review
- Administrative manual
- Staff interviews

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

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## Subrecipient Monitoring

### **Expectation 1:**

Detail a plan for monitoring the delivery of family planning services under the Title X project, including the monitoring and oversight of subrecipients. (45 CFR § 75.352)

#### **Review of Evidence Demonstrating Compliance (A):**

- TDH Family Planning Administrative Manual
- 2022 Family Planning Audit Schedule

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** The Federal and State Monitoring Visit section of the FP Administrative Manual declares contract agencies will be visited at least every three years. Currently, FPP staff conduct a site visit to every clinic site during the project period. This schedule takes a lot of staff time and a chunk of the travel budget. FPP Project Director is going to consider reviewing a sample of clinic sites during the project period. This should be as effective as reviewing every clinic site and less of a drain on resources. All Metro clinics will be reviewed during the project period. TFPP plans to modify the federal review tool for their use.*

### **Expectation 2:**

In accepting the award, agree that the award and any activities thereunder are subject to all provisions of 45 C.F.R. part 75, currently in effect or implemented during the period of the award, (PA-FPH-22-001 NOFO and Notice of Award Special Terms and Expectations)

#### **Review of Evidence Demonstrating Compliance (F):**

- Review of contracts with metropolitan area health departments

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** N/A*

### **Expectation 3:**

In accordance with 45 CFR § 75.352(d), monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes,

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regulations, and the terms and conditions of the subaward; and that subaward performance goals are achieved. Recipient monitoring of the subrecipient must include:

- i. Reviewing financial and performance reports required by the recipient.
- ii. Following-up and ensuring that the subrecipient takes timely and appropriate action on all deficiencies pertaining to the Federal award provided to the subrecipient from the recipient detected through audits, on-site reviews, and other means.
- iii. Issuing a management decision for audit findings pertaining to the Federal award provided to the subrecipient from the recipient as required by 45 CFR § 75.521.

**Review of Evidence Demonstrating Compliance (A):**

- Sample subrecipient contract
- Hamilton County Contract
- SER Site Visit tool 5/18/22
- Chattanooga-Hamilton Title X Site Review tool 10/22/19
- TFPP Audit Schedule
- Chattanooga-Hamilton CHD and Polk CHD site review reports

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The sample subrecipient contract and the Hamilton County contract require subrecipients to provide services in compliance with TDH FPP Administrative Manual and Program Requirements for Title X Funded Family Planning Projects. The latter document is no longer in use and has been replaced by the Title X Program Handbook. Site visit reports for monitoring visits to Hamilton County and SER were provided for review. No deficiencies were found for Hamilton County. SER had a non-compliance finding regarding the I&E/advisory committee and review process. SER FPA has organized a committee and will convene an I&E Advisory Committee meeting in 2022.*

- *SER 2020 site visit tool showed non-compliance related to I&E/Advisory Committee functions. The committee is not active and has not met.*
- *The Chattanooga-Hamilton Health Department Title X site review tool did not identify any administrative issues. The consultant recommended training through RHNTC.*

*Site visits were not done during 2021 due to COVID and travel restrictions. FPA documentation for the site visit to Hamilton County Health Department on 3/28/22 was provided for review. Comprehensive review documented on the checklist with comments as needed. No issues were identified.*

**Best Practice Suggestion:**

- *Revise contracts with subrecipients to remove the reference to "Program Requirements for Title X Funded Family Planning Projects" and add the newly released document, Title X Program Handbook.*
- *Revise A.6.d. of contracts with subrecipients to include verification of training regarding encouraging family involvement in the decision of minors to seek reproductive health services*

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*and counseling minors on how to resist attempts to coerce minors into engaging in sexual activities.*

- *Revise D.10. Nondiscrimination section of subrecipient contracts to include sexual orientation, gender identity, and sex characteristics.*

**Review of Evidence Demonstrating Compliance (F):**

- Subrecipient contract
- Subrecipient billing and payment
- Chart reviews
- Budget review

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 4:**

Depending upon the recipient's assessment of risk posed by the subrecipient, employ the following monitoring tools that may be useful for the recipient to ensure proper accountability and compliance with program expectations and achievement of performance goals: providing subrecipients with training and technical assistance on program-related matters; and performing on-site reviews of the subrecipient's program operations; and arranging for agreed-upon-procedures engagements as described in 45 CFR § 75.425. (45 CFR § 75.352(e))

**Review of Evidence Demonstrating Compliance (F):**

- Interviews regarding subrecipient site visits by health department staff

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 5:**

Verify that every subrecipient is audited as required by Subpart F of 45 CFR Part § 75 when it is expected that the subrecipient's Federal awards expended during the respective fiscal year equaled or exceeded the threshold set forth in 45 CFR § 75.501. (45 CFR § 75.352(f))

**Review of Evidence Demonstrating Compliance (F):**

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- Audit

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 6:**

Consider whether the results of the subrecipient's audits, on-site reviews, or other monitoring indicate conditions that necessitate adjustments to the recipient's own records. (45 CFR § 75.352(g)).

**Review of Evidence Demonstrating Compliance (F):**

- Subrecipient monitoring documentations

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** Subrecipient monitoring documentation does not indicate that adjustments were needed.

**Expectation 7:**

Consider taking enforcement action against noncompliant subrecipients as described in 45 CFR § 75.371 and in program regulations. (45 CFR § 75.352(h))

**Review of Evidence Demonstrating Compliance (F):**

- Interviews with subrecipient and state health department staff

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 8:**

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Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project. (42 CFR § 59.5(a)(11)(ii))

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures
- Subrecipient Inclusion in Policy Establishment (Eff date 4/1/22; revision date 3/22/22)

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP policy states TFPP and TDH will provide opportunity(s) for contracted agencies and TDH staff to participate in the establishment of ongoing grantee policies and guidelines. TFPP collaborates with statewide TFPP administrators and multiple and diverse stakeholders to encourage engagement in guidelines development and implementation. Proposed policies, processes, standards, and procedures are developed in collaboration with TDH Community Health Services. The PHNP committee reviews and updates public health nursing protocols. This Committee includes one PHN from each rural region and one from two of the metropolitan areas. The Medical Leadership Team provides medical guidance, reviews, and updates to PH protocols. Proposed policies (or modifications to existing policies) are presented to the policy review committee for review and recommendation. Additional input comes from the following: monthly FPA meetings, biannual MCH stakeholders' meetings, continuing education of health care partners and staff in clinical guidelines, and community health communication campaigns and education. Regional and Metro Family Planning Administrator meeting PowerPoint presentations were provided for review, but meeting minutes were not recorded. TFPP should document input from FPAs.*

*Best Practice Suggestion: The recipient should maintain minutes of meetings with FPAs. The minutes should document suggestions for new policies and suggestions/changes to existing policies and procedures, forms, or other material. Provide feedback to FPAs regarding action taken related to their input, if any.*

## Community Education, Participation, and Engagement

### Expectation 1:

Provide for opportunities for community education, participation, and engagement to: achieve community understanding of the objectives of the program; inform the community of the availability of services; and promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services. (42 CFR § 59.5(b)(3))

#### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Community Awareness and Education (eff 4/1/22; rev 3/4/22)
- State of TN and TDH website
- Chattanooga-Hamilton County Community Outreach and Education Program Area Annual Action Plan FY 2022
- South East Family Planning Outreach Plan 2022-2023
- Hamilton County Family Planning Outreach Plan 2022-2023

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP has a written policy and procedures to ensure compliance with this expectation. TFPP developed a community outreach and Education Program Area Annual Action Plan FY22. The plan describes TFPP and health education staff efforts to make services known to the target population. FPAs are required to establish and implement community education and promotional activities. Outreach and education plans were provided for Hamilton Metro and SER for FY22 and FY 23. The Plans reflect Metro or Region activities for Recipient goals, objectives, and activities. Promotion and outreach activities are reviewed biannually by the FPA. Community outreach and education activities were prohibited due to COVID in FY20 and 21. Some outreach activities have or will take place this fiscal year. Another outreach tool is the Tennessee Department of Health website. Information is available no matter what language the user speaks and reads. The website can be translated into a variety of languages. The Family Planning section of the website advertises telehealth services and includes the phone number for an appointment. The site includes the following pages: educational resources, family planning services, healthcare provider resources, and Title X information. The family planning services page includes the OASH Office of Population Affairs Find a Family Planning Clinic tool. In addition to a list of family planning services, the page informs clients that services are confidential, teens or adults are not subjected to discrimination, fees are based on a sliding fee scale, and no one is turned away due to inability to pay.*

### Expectation 2:

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Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services. (42 CFR § 59.5(b)(10))

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Collaborative Planning and Community Engagement (eff 4/1/22; rev 3/4/22)
- Subrecipient Inclusion in Policy Establishment (eff 4/1/22, rev 3/22/22)
- Polk County and Hamilton County Health Departments I&E/Advisory Committee meetings documentation

This expectation was **MET**.

**Areas of Improvement and Required Action (A): N/A**

**Technical Assistance: N/A**

*Best Practices Suggestions & Additional Comments: TDH TFPP Collaborative Planning and Community Engagement policy and procedure describe the process for compliance with this expectation. The policy procedure indicates the I&E Advisory Committee or a separate group will serve in the community participation role. The Advisory Committee membership for the two clinic sites reviewed is limited and may not include individuals who are knowledgeable about the family planning needs of the community.*

*I&E/Advisory Committees reviewed at both sites (Chattanooga-Hamilton CHD and Polk County Health Department) document committees reviewed the work plan and other information was presented to the committees but do not include recommendations/comments provided by committee members.*

*TDH does not have a written community engagement plan.*

*The reviewer discussed options for meeting this expectation. For example, TFPP may require FPAs to expand the size and scope of their I&E Advisory Committees to include representatives from the community whose focus is reproductive health or seek input from community groups with a membership that is knowledgeable about reproductive health needs.*

*Best Practice Suggestion: The recipient should develop a community engagement plan which describes their process for obtaining input from community members and individuals from the community knowledgeable about the need for family planning services. Maintain documentation of the implementation of the plan.*

## Information and Education (I & E)

### Expectation 1:

Have an advisory committee (sometimes referred to as information and education committee) that reviews and approves print and electronic informational and educational materials developed or made available under the project, prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X. The project shall not disseminate any materials which are not approved by the advisory committee. (Section 1006(d)(1) and (2), PHS Act; 42 CFR § 59.6(a))

#### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Materials Review and Approval Process (eff 4/1/22; rev 3/4/22)
- Hamilton CHD I&E Committee Meeting documentation 2020
- Hamilton CHD I&E Advisory Council meeting (3/23/22)
- Hamilton CHD Materials Approved Reference Chart (updated 6/13/22)
- SER I&E Inventory Log

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** The I&E Materials Review and Approval Process policy and procedure requires each region, metro, or contracted Family Planning administrator should establish and implement a material review and approval process for their service sites. FPAs are required to submit minutes for I&E Advisory committee minutes to the central office (TDH FP office in Nashville). The process complies with Title X expectations. Monitoring reports document monitoring for compliance with this expectation. FPP has adopted RHNTC instructions and templates for the I&E materials review process. These documents are on the TFPP shared drive.*

*Hamilton CHD 2020 I&E Committee Meeting documentation shows there are 9 members on the committee but only 3 participated in this email meeting. The material should be reviewed and approved by a majority of the committee members. The documentation was sent to the FPP Administrator. There was no documentation to show feedback.*

### Expectation 2:

Think specifically about the print and electronic materials they are making available to Title X clients under the Title X project when considering which materials require review and approval by the advisory committee. For Title X projects that provide non-Title X services (e.g., hospitals, health centers), this does not include all possible materials that a Title X client may find on the organization's website or as they walk through the building, but only those specific materials that

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are made available to the Title X client under the Title X project and those materials developed specifically for the Title X client. (2021 Final Rule FAQs)

**Review of Evidence Demonstrating Compliance (A):**

- Metro/region I&E materials (print or electronic) inventory
- Interviews with TFPP Director and FPAs

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *A review of Hamilton and SER I&E materials and websites reviewed, and approved inventory shows the documents and websites are relevant for the project. The Hamilton County inventory included some material that has not been reviewed since 2012.*

*Best Practice Suggestion: The recipient should recommend regions and metros and ask their materials review committees to review material currently in use every 3 to 5 years.*

**Expectation 3:**

Establish and maintain an advisory committee that:

- i. consists of no fewer than five members and up to as many members the recipient determines; and
- ii. includes individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality). (Section 1006(d)(2), PHS Act; 42 CFR § 59.6(b))

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, I&E Advisory Committee Requirements
- TN Family Planning Policy and Procedures, Advisory Committee Responsibility for I&E Materials
- TN Family Planning Program Policy and Procedures, I&E Materials Review and Approval Process
- 2022 Administrative Manual, Information & Education Advisory Committee and Material Approval
- Hamilton CHD I&E Committee Meeting documentation (2020)
- Hamilton CHD Advisory Council Minutes (3/23/22)

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- SER Community Input Committee and Materials Review Minutes

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The Recipient has established policies and procedures which are in compliance with Title X expectations. The function is delegated to Regions/Metros or other contracted agencies. Central office staff monitor metros and regions for compliance. Meeting minutes do not document who reviewed the factual, technical, and clinical accuracy of the material. Hamilton County demographic forms for the Advisory Committee show the committee has eight members, five are white and one is African-American/Black. Five members are between the ages of 23 and 32. Hamilton County population's race and ethnicity show 68% white, 17% Black or African American, 2% Asian, and 7% Hispanic.*

*Hamilton CHD Advisory Council Minutes submitted for the 3/23/22 meeting show a committee of eight members. Demographic forms were submitted for six of the members.*

*SER Community Input (2020): Minutes include documentation provided. Document review sheets for documents would have been helpful, but the minutes include criteria considered when reviewing the documents. The FPA has organized a new committee and plans to convene a meeting this year.*

*Best Practice: Recommend grant recipient modify I&E Materials Review and Approval Process policy to include (e.g., print and electronic) to agree with the 2021 Final Rule.*

*Best Practice: The recipient should ensure I&E/Advisory Committees' membership is broadly representative of the community served (including non-white, teens, LGBTQ+, etc.) and others in the community who are knowledgeable about the need for family planning services.*

**Expectation 4:**

Ensure that the advisory committee, in reviewing materials:

- consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;
- consider the standards of the population or community to be served with respect to such materials;
- review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;
- determine whether the material is suitable for the population or community to which is to be made available; and
- establish and maintain a written record of its determinations. (Section 1006(d)(1), PHS Act; 42 CFR § 59.6(b))

**Review of Evidence Demonstrating Compliance (A):**

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- TN Family Planning Program Policy and Procedures, I&E Advisory Committee Membership (eff 4/1/22; rev 3/4/22)
- TN Family Planning Program Policy and Procedures, Advisory Committee Responsibility for I&E Materials Review (eff 4/1/22; rev 3/4/22)
- Hamilton CHD 2020 Family Planning I&E Committee Meeting Minutes, Committee members' demographic forms
- SER Advisory Committee members demographic forms

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TFPP has established policies and procedures for complying with these expectations. TFPP policy requires appropriate project staff to review the factual, technical, and clinical accuracy of all I&E materials developed or made available under the Title X project. Meeting minutes document the material was reviewed and approved. Review forms guide the review to assure the committee reviews the material for education level, cultural and diverse background of the community, standards of the community, and suitability for the community. TFPP policy states that TFPP will ensure that appropriate project staff reviews the factual, technical, and clinical accuracy of all I&E materials developed or made available to the Title X project. Site visit reports show recipients monitor for compliance with these expectations.*

*Each region is required to have an I&E Advisory Committee to review all materials and ensure they are appropriate for identified/targeted populations.*

*Hamilton CHD I&E Committee Meeting documentation is for 2020. The diversity of the committee looks good, but based on the meeting participation (e.g., via email) members are not active. Only three members participated in the email meeting. This number is less than half the committee. The documentation was emailed to the FPP Administrator. The 3/23/22 meeting minutes include a description of the project information provided to the committee, but do not document if the committee was given an opportunity to provide input. The county is very diverse, but the committee membership has one African American and the remaining five are white. The committee does have two males. Five members are between the ages of 23 and 32.*

**Best Practice Suggestion:** *The recipient should ensure that I&E/Advisory Committee meeting minutes document committee members were given an opportunity to provide suggestions/comments related to the program information provided.*

## Staff Training

### **Expectation 1:**

Provide for orientation and in-service training for all project personnel. (42 CFR § 59.5(b)(4))

#### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Staff Training and Project Technical Assistance (Eff 4/1/22; Rev 3/2022)
- TDH Family Planning Administrative Manual (03/22), Training Requirements for Family Planning Staff
- PHN Orientation & Practice Manual 2022 (rev 4/22)
- 2021 Annual Family Planning Training
- Family Planning Training Plan

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:** PHN Orientation & Practice Manual 2022 Section III Orientation Guidelines for Nursing Personnel defines the orientation process for new public health nurses. The assigned preceptor and local health department staff work with the orientee to provide guidance and support in implementing the orientation plan. Skills are demonstrated and the orientee's competent return demonstration is documented on the Skills Orientation Checklist.*

*The grant recipient has a robust training program. Staff complete training from the RHNTC and training developed in-house. Acknowledgment forms for training are signed when training is complete and certificates of completion are attached.*

*The Title X Requirements Acknowledgement form can be used to acknowledge that FP staff have read and understand key Title X expectations such as non-discrimination, voluntary services, non-coercion, prohibitions on abortion, client confidentiality, and translation services.*

*Certificates of Completion for the 2021 National Reproductive Health Conference: Virtually Unstoppable were submitted to staff in SER and Hamilton.*

*2021 Annual Family Planning Training must be revised to reflect the changes in the Final Rule.*

### **Expectation 2:**

Ensure routine training of staff on Federal/State expectations for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, as well as on human trafficking. (Legislative Mandate set out in the Annual HHS Appropriations Act)

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OPA's expectation is that routine training would happen on an annual basis. In addition, OPA recommends Title X recipients and subrecipients provide routine training in accordance with the RHNTC's Title X Training Expectations Summary Job Aid.

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Staff Training, and Project Technical Assistance.
- TN Family Planning Program Policy and Procedures, Compliance with Legislative Mandates (eff 4/1/22; rev 3/2022)
- TDH Family Planning Administrative Manual (03/22), Training Requirements for Family Planning Staff
- Title X Family Planning Training Plan (11/21)
- Title X: Mandatory Reporting Acknowledgement form
- Human Trafficking 2022 Training Acknowledgement form
- Hamilton CHD Title X Mandatory Training Verification Report FY 22
- SER staff PHN Orientation Checklist (2022)
- SER annual FP mandatory training

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TDH policy requires all TFPP staff to complete annual training on laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, intimate partner violence, as well as on human trafficking; and annual training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.*

*TFPP Clinical Trainer sends emails to staff with training acknowledgment forms for required training attached. These acknowledgment forms include links to the training provider site (RHNTC, state, etc.). Staff will receive reminder emails until the completed form with certificates of completion attached are returned to the TFPP Clinical Trainer. The Training Plan provided for review included all FPP staff training on these topics upon initial employment orientation and at least annually thereafter. Spreadsheets showing training completed by Hamilton Metro and SER. The Clinical Services Training.*

*Legislative Mandates Policy: State recipients will adhere to legislative mandates through policy creation, implementation, and monitoring.*

*Administrative Manual: Training requirements for Family Planning Staff list include training on Family Planning policies and procedures as follows: Family Planning Policies and Procedures, Title X Requirements and Priority Areas, Mandatory Report (Child Abuse), Intimate Partner Violence, Human Trafficking, Cultural Competency, and Sexual coercion avoidance education for adolescents.*

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*The Title X Training Plan lists the following annual training: Voluntary Participation, Acceptance of Family Planning Services not a Prerequisite for Eligibility or Services, Prohibition of Abortion, Confidentiality, Cultural Competency/Humility, Facilities and Accessibility of Services, Mandatory Report, State, Human Trafficking, Family Involvement, Counseling Minors to Resist Sexual Coercion, and Non-Discrimination.*

**Expectation 3:**

Ensure routine training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities. (Legislative Mandate set out in the Annual HHS Appropriations Act)

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Staff Training and Project Technical Assistance.
- Title X Consideration of Minors Acknowledgement form
- TDH Family Planning Administrative Manual (03/22), Training Requirements for Family Planning Staff
- Title X Family Planning Training Plan (11/21)
- Documentation of training

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** Policy shows new TFPP staff are required to complete a project orientation that includes involving family members in the decision of minors to seek FP services and on counseling minors on how to resist being coerced into engaging in sexual activities. The Training Plan for TFPP staff including training on these expectations.

*Documentation of training on these expectations was provided for review. Title X Consideration of Minors Acknowledgement form along with certificates of completion may be used to document family planning staff have completed the RHNTC training Counseling Adolescent Clients to Encourage Family Participation and Counseling Adolescent Clients to Resist Sexual Coercion.*

## Quality Improvement and Quality Assurance (QI & QA)

### **Expectation 1:**

Develop and implement a quality improvement and quality assurance plan that involves collecting and using data to monitor the delivery of quality family planning services, inform modifications to the provision of services, inform oversight and decision-making regarding the provision of services, and assess patient satisfaction. (PA-FPH-22-001 NOFO and Notice of Award Special Terms and Expectations)

### **Review of Evidence Demonstrating Compliance (A):**

- FY 22 Competitive Application State of Tennessee
- Patient Tracking (PTBMIS)
- Quality Assurance & Improvement Manual (July 2021)
- TN Family Planning Administrative Manual
- FPAR Reports (2021, 2019-2022)
- Site Visit Reports

This expectation was **MET**.

### **Areas of Improvement and Required Action (A):** N/A

### **Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The TFPP program currently uses TDH's Patient Tracking Billing Management Information System (PTBMIS) to collect client encounter data. TFPP will transition to FPAR 2.0 beginning in CY2022 and will report partial record-level data and the preferred approach outlined in the FPAR 2.0 Implementation Guide (October 2021). TDH is in the process of implementing a new EHR and phasing out the current system.*

*The QI/QA Work Plan includes calculating by state and by demographic/geographic subgroups contraceptive care performance measures: 1) the percentage of women aged 15-44 years at risk of unintended pregnancy that is provided a most effective or moderating effective contraceptive method, and 2) the percentage of women aged 15-44 years at risk of unintended pregnancy that is provided a long-acting reversible contraceptive method. Additional plans include piloting the use of the Person-Centered Contraceptive Counseling (PCCC) measure created by the University of California San Francisco at one or more clinics, and a FP telehealth client satisfaction survey. TDH does not have a QI/QA policy and procedure.*

*Templates were provided for Hamilton County Health Department for chart and facility audits. A completed chart audit report was also provided. A 30-day Improvement Plan for the 10/12/21 site visit was available for review.*

### **Review of Evidence Demonstrating Compliance (C):**

- Recipient policy and procedures regarding QI/QA
- Recipient QI/QA Work Plan
- Clinic Review tools Family planning Telehealth Study, February 2022

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- Patient Satisfaction Results

This expectation was **MET**.

**Areas of Improvement and Required Action (C): N/A**

**Technical Assistance:** TFPP has over 120 sites in 13 regions which they attempt to review once each grant cycle. The reviewer discussed ways to prioritize which sites to review, e.g., those perceived to have challenges, in order to make these reviews more manageable for the 3-person review team that travels year-round.

**Best Practices Suggestions & Additional Comments:** *Recipient staff conduct site visits to review staff performance in clinical care, fiscal responsibility, and program administration at every project site at least once every project period. If deficiencies are identified during the site visit, a corrective action plan is assigned. The TFPP has procedures in place to follow up and ensure the implementation of the corrective action plan.*

**Expectation 2:**

Address oversight and service provision at the recipient level, the subrecipient level, and the service site level within their QI/QA plan. (PA-FPH-22-001 NOFO and Notice of Award Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (A):**

- Quality Assurance & Improvement Manual (July 2021)
- Office of Quality Improvement meeting minutes

This expectation was **MET**

**Areas of Improvement and Required Action (A): N/A**

**Technical Assistance: N/A**

**Best Practices Suggestions & Additional Comments:** *Chattanooga-Hamilton County Health Department Quality Improvement Office does chart reviews, credentialing, risk minimization audits, internal lab training and check-offs, and help with the maintenance of equipment (e.g., timing for service), infection control, and help in updating protocols. Deficiencies identified require corrective action plans. Chart audits on new employees and each clinic site have general chart audits every six months. Peer audits are completed two times per year. Proficiency testing for CLIA lab certification.*

**Expectation 3:**

Submit a Family Planning Annual Report (FPAR). The information collection (reporting expectations) and format for this report have been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0990-0479 (Expires 9/30/2024). The FPAR data elements, instrument, and instructions are found on the OPA Web site at <http://opa.hhs.gov>. Recipients are

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expected to use the FPAR data to inform their QI/QA activities. (PA-FPH-22-001 NOFO and Notice of Award Special Terms and Expectations)

**Review of Evidence Demonstrating Compliance (A):**

- FY 22 Competitive Application State of Tennessee
- TN Family Planning Administrative Manual
- Chattanooga-Hamilton CHD QI Office
- FPAR (by clinic level, metro, regional)

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *Considering the impact of COVID, FPAR looks fairly reasonable. The number and percent of users who are male is very low (less than 3%). The 3-year report also shows the percentage of users that were male has been low over the 3-year period. TN FPP staff is working on improving these numbers, specifically working with the STD program to provide family planning services information for male clients.*

*Epidemiologist utilizes family planning service information (FPAR) in combination with mapping to identify outreach areas. She has generated a variety of maps for the TFPP Project Director.*

*TN Family Planning Administrative Manual, Family Planning Annual Report section states TFPP uses TDH's Patient Tracking Billing Management Information System (PTBMIS) and the EHR to collect client encounter data. All metro and local health departments currently report data from client encounters through PTBMIS.*

# Prohibition of Abortion

## Expectation 1:

Not provide abortion as a method of family planning as part of their Title X project. (Section 1008, PHS Act; 42 CFR § 59.5(a)(5))

### **Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Prohibition of Abortion & Referral for Abortion (Effective Date 4/1/22 Revision Date 3/4/22)
- 2010 Tennessee Code Title 9 - Public Finances, Chapter 4 - State Funds, State Budget and Appropriations, Part 51 - State Budget and Appropriations 9-4-5116 - Abortion Funding
- TN Family Planning Administrative Manual (March 2022)
- Subrecipient contracts
- TN PHN Protocols
- Hamilton County Health Department Family Planning Standards 2021 (rev 04/04/22)

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *TN Family Planning Program has established policies and procedures stating that the project does not provide abortion as a method of family planning. The policy requires TFPP Family Planning staff to offer clients with positive pregnancy tests all options counseling and referrals upon request. Following the release, staff will provide neutral, factual information and nondirective counseling, and referral upon request on the options the pregnant client expressed an interest in. Grant recipient contracts and subcontracts must include language addressing this expectation and documentation of the training provided. Subrecipient contracts prohibit subrecipient agencies from using Title X funds for abortion or abortion-related services. The contract requires compliance with the TN Family Planning Program Administration Manual. Following the release of the 2021 Final Rule, TDH issued a Program Memorandum (11/7/21) that included a description of changes included in this rule. The memorandum included a brief description of the expectation to offer pregnant clients all options for counseling and referral (upon request). Staff signed a 2021 Final Federal Rule Title X Rule Changes Acknowledgement form. Subrecipient contracts prohibit subrecipient agencies from using Title X funds for abortion or abortion-related services to comply with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5). The contract requires compliance with Title X and the TN Family Planning Program Administration Manual.*

*TN AB law prohibits the use of state funds for abortion services with two exceptions: pregnancy is the result of rape or incest, or a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself.*

## Expectation 2:

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Prohibit providing services that directly facilitate the use of abortion as a method of family planning, such as providing transportation for an abortion, explaining and obtaining signed abortion consent forms from clients interested in abortions, negotiating a reduction in fees for an abortion, and scheduling or arranging for the performance of an abortion, promoting or advocating abortion within Title X program activities, or failing to preserve sufficient separation between Title X program activities and abortion-related activities. (65 Fed. Reg. 41281 (July 3, 2000))

**Review of Evidence Demonstrating Compliance (A):**

- TN Family Planning Program Policy and Procedures, Prohibition of Abortion & Referral for Abortion (Effective Date 4/1/22 Revision Date 3/4/22)
- PHN Protocol, Pregnancy Testing
- TN Family Planning Program Policy and Procedures, Conscientious Objection to Abortion Counseling & Referral
- Subrecipient contract
- TN Family Planning Program Administrative Manual
- TN Department of Health Title X Assurances signed by Assistant Commissioner (1/10/2019)
- Hamilton County Health Department Family Planning Standards 2021 (rev 04/04/22)
- Subrecipient contract

This expectation was **MET**.

**Areas of Improvement and Required Action (A): N/A**

**Technical Assistance: N/A**

**Best Practices Suggestions & Additional Comments:** *Grant recipient established policies and procedures to describe the process for ensuring compliance with expectations that prohibit providing, promoting, referring for, or supporting abortion as a method of family planning, and referring to abortion as a method of family planning. Policies and protocols are in compliance with Title X expectations and the 2021 Final Rule.*

*TN Family Planning Program Policy and Procedures, Prohibition of Abortion & Referral for Abortion complies with Final Rule. PHN Protocol, Pregnancy Testing, aligns with the Final Rule. The protocol does allow for PHNs with a conscientious objection to counseling on termination to turn the client over to someone to do that counseling. It could be another staff member or FP telehealth services to meet the client's needs.*

*Conscientious Objection to Abortion Counseling & Referral policy establishes a policy and procedure for clinical staff who declare a conscientious objection to pregnancy termination to immediately defer pregnancy and all options counseling to another clinician.*

*Subrecipient contracts prohibit the use of Title X funds for abortion or abortion-related services in compliance with section 1008.*

**Expectation 3:**

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Prohibit promoting or encouraging the use of abortion as a method of family planning through advocacy activities such as providing speakers to debate in opposition to anti-abortion speakers, bringing legal action to liberalize statutes relating to abortion, or producing and/or showing films that encourage or promote a favorable attitude toward abortion as a method of family planning. Films that present only neutral, factual information about abortion are permissible. A Title X project may be a dues paying participant in a national abortion advocacy organization, so long as there are other legitimate program-related reasons for the affiliation (such as access to certain information or data useful to the Title X project). A Title X project may also discuss abortion as an available alternative when a family planning method fails in a discussion of relative risks of various methods of contraception. (65 Fed. Reg. 41281, 41282 (July 3, 2000))

**Review of Evidence Demonstrating Compliance (A):**

- Interviews with Project Director

This expectation was **MET**.

**Areas of Improvement and Required Action (A):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The recipient does not participate in prohibited activities.*

*In addition, the Director stated that TDH service sites are allowed to provide resource lists to clients seeking information on pregnancy termination sites. TDH FPP forms, policies, etc. are under review by TDH legal staff and expect a decision on what they are allowed to provide to or say to clients seeking pregnancy termination counseling and referral. Staff are concerned they will not be allowed to provide counseling. No pregnancy termination/abortion brochures are available to clients.*

**Expectation 4:**

Ensure that non-Title X abortion activities are separate and distinct from Title X project activities. Where recipients conduct abortion activities that are not part of the Title X project and would not be permissible if they were, the recipient must ensure that the Title X-supported project is separate and distinguishable from those other activities. What must be looked at is whether the abortion element in a program of family planning services is so large and so intimately related to all aspects of the program as to make it difficult or impossible to separate the eligible and non-eligible items of cost. The Title X project is the set of activities the recipient agreed to perform in the relevant grant documents as a condition of receiving Title X funds. A grant applicant may include both project and non-project activities in its grant application, and, so long as these are properly distinguished from each other and prohibited activities are not reflected in the amount of the total approved budget, no problem is created. Separation of Title X from abortion activities does not require separate recipients or even a separate health facility, but separate bookkeeping entries alone will not satisfy the spirit of the law. Mere technical allocation of funds, attributing federal dollars to non-abortion activities, is not a legally supportable avoidance of section 1008. Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities:

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- i. a common waiting room is permissible, as long as the costs properly pro-rated,
- ii. common staff is permissible, so long as salaries are properly allocated, and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project,
- iii. a hospital offering abortions for family planning purposes and also housing a Title X project is permissible, as long as the abortion activities are sufficiently separate from the Title X project, and
- iv. maintenance of a single file system for abortion and family planning patients is permissible, so long as costs are properly allocated. (65 Fed. Reg. 41281, 41282 (July 3, 2000))

**Review of Evidence Demonstrating Compliance (F):**

- Review of administrative manuals
- Tour of service sites
- Review of cost allocations
- Review of invoicing
- Review of services being provided

This expectation was **MET**.

**Areas of Improvement and Required Action (F):** N/A

**Technical Assistance:** N/A

***Best Practices Suggestions & Additional Comments:*** N/A

**Expectation 5:**

A Title X project may not provide pregnancy options counseling which promotes abortion or encourages persons to obtain abortion, although the project may provide patients with complete factual information about all medical options and the accompanying risks and benefits. While a Title X project may provide a referral for abortion, which may include providing a patient with the name, address, telephone number, and other relevant factual information (such as whether the provider accepts Medicaid, charges, etc.) about an abortion provider, the project may not take further affirmative action (such as negotiating a fee reduction, making an appointment, providing transportation) to secure abortion services for the patient. (65 Fed. Reg. 41281 (July 3, 2000))

**Review of Evidence Demonstrating Compliance (C):**

- Pregnancy Testing Policy
- Staff interview

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

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**Technical Assistance:** The reviewer recommended that the Polk-Benton clinic include abortion providers in nearby states (since there are no abortion providers in Tennessee) for those patients requesting this information due to an unintended pregnancy.

**Best Practices Suggestions & Additional Comments:** *All staff have received training regarding the prohibition of abortion-related activities.*

**Expectation 6:**

Where a referral to another provider who might perform an abortion is medically indicated because of the patient's condition or the condition of the fetus (such as where the woman's life would be endangered), such a referral by a Title X project is not prohibited by section 1008 and is required by 42 CFR § 59.5(b)(1). The limitations on referrals do not apply in cases in which a referral is made for medical indications. (65 Fed. Reg. 41281 (July 3, 2000))

**Review of Evidence Demonstrating Compliance (C):**

- Staff interviews
- Pregnancy protocol
- Pregnancy referral list (Hamilton)

This expectation was **MET**.

**Areas of Improvement and Required Action (C):** N/A

**Technical Assistance:** N/A

**Best Practices Suggestions & Additional Comments:** *The grant recipient is compliant with this expectation.*

## Quality Family Planning Implementation Assessment

This portion of the assessment follows the recommendations detailed in Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (QFP), which focuses on service provision consistent with the best available scientific evidence.

**\*\*\*Please review the QFP Clinical Assessment Checklist (Supplement Review Tool for Admin and Clinical reviewers) separately submitted.**





**FAMILY PLANNING  
ADMINISTRATIVE MANUAL**

Family Health and Wellness Division

*Revised March 2022*



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## ACKNOWLEDGEMENTS

**This manual has been revised and updated with the assistance of the following:**

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## FAMILY PLANNING ADMINISTRATOR SIGNATURE PAGE

Date: \_\_\_\_\_

The Family Planning Administrative Manual must be reviewed and signed annually by the Family Planning Administrator. It is the responsibility of the Family Planning Administrator to ensure all staff working on the Title X program, are up to date with Title X policy and procedure. Signature pages must be available for review during TFPP site visits.

With the signature below, the Title X agency authorizes that it has read and implemented required administrative elements into the Family Planning program.

\_\_\_\_\_ Family Planning Administrator  
(printed name)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_





## FAMILY PLANNING ADMINISTRATOR LETTER

March 2022

Dear Family Planning Administrator:

Thank you for reviewing this Administrative Manual and utilizing the policy and procedures of Title X and the Tennessee Family Planning Program in your clinical practice. This manual is designed by the Tennessee Department of Health's Family Planning Program (TFPP) staff to help guide clinics through the administrative regulations of the Title X Family Planning Program. To read the federal Title X Program Requirements, please visit: <https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates>

The Tennessee Family Planning Program must have written policies in accordance with Title X statutes and regulations. The policies, procedures, and strategies in which the family planning program operates must demonstrate compliance with the requirements of the Title X Program. Contracted agencies are required to maintain policies and procedures specific to their organizations and ensure they meet the requirements of Title X.

This manual mirrors the Title X Family Planning Program regulations and the 2014 Program Requirements for Title X Funded Family Planning Projects document. These Federal regulations are translated into the Tennessee context.

<https://opa.hhs.gov/sites/default/files/2021-03/title-x-program-requirements-april-2014.pdf>

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### TITLE X REGULATIONS

Project Grants for Family Planning Services - <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A>

Grants for Family Planning Service Training - <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-C>

Compliance With Statutory Program Integrity Requirements *Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services*. A Rule by the Health and Human Services Department on 10/07/2021

<https://www.federalregister.gov/documents/2021/10/07/2021-21542/ensuring-access-to-equitable-affordable-client-centered-quality-family-planning-services>

This Administrative Manual outlines policies and procedures applicable to all family planning clinic sites. Some variations in management are anticipated and appropriate, but many aspects of the program must be consistent and uniform throughout the state. This manual serves as a reference point for federal, state, and program requirements.

This Manual contains sections dealing with the project management and administration, project services and clients, financial management, community participation, education, and project promotion, information and education materials review, and additional administrative requirements.

Every reasonable effort will be made to keep this manual current. If service sites find errors in content, they are encouraged to contact the key TFPP central office staff so that concerns may be addressed, and changes made to the manual as needed. TFPP staff will make updates to this document at least annually. It is the responsibility of the Family Planning Administrator (FPA) to ensure appropriate staff has read and reviewed the updated manual and sign the "Signature Page" annually.

If you have any questions or see an area for improvement, please send your comments to [Danni.Lambert@tn.gov](mailto:Danni.Lambert@tn.gov). We thank you for your collaboration and your service to Tennesseans.

Sincerely,

*The Tennessee Department of Health's Family Planning Program Staff*

*Disclaimer: This document provides links as a convenience to users and may require additional searches by the user to extract specific information. The TFPP does not exercise any editorial control over the information and functionality of the external hyperlinks. According to the document review schedule, these links will be reviewed and revised as needed.*

## TENNESSEE FAMILY PLANNING PROGRAM PURPOSE & MISSION

The mission of the Tennessee Department of Health (TDH) is to *Protect, Promote and Improve the health and prosperity of people in Tennessee*. The vision of the Tennessee Department of Health (TDH) is to be a recognized and trusted leader, partnering and engaging to accelerate Tennessee to one of the nation's ten healthiest states. Our values include:

- Teamwork
- Integrity
- Mutual Respect
- Excellence
- Compassion
- Servant Leadership.

The Tennessee Family Planning Program aims to improve health outcomes for individuals of reproductive age, and advance health equity through the delivery of comprehensive, high-quality family planning services that are client-centered, culturally, and linguistically appropriate, inclusive, and trauma-informed. The program provides a broad range of services related to achieving pregnancy, preventing pregnancy, assisting individuals and couples with achieving their desired number and spacing of children, and reducing the incidence of sexually transmitted infections (STIs). TFPP provides comprehensive family planning and related preventive health services to everyone requesting services, low-income emphasizing low-income, high-risk, minority, historically underserved, marginalized, and adolescent clients.

Tennessee has a long tradition of providing family planning services to women in the public health sector. Long before the term “Family Planning Clinic” was coined, health departments across the state provided services in half-day sessions called “Pap Smear” or “Birth Control Clinics.” The health officer and public health nurse usually ran these clinics. Contraceptive supplies were limited to a few brands of oral contraceptives and to IUDs that were sterilized on-site (in surgical basins) just before insertion. Tennessee has come a long way. The following are some landmark dates for the program.

- **1930’s** Birth control clinics in hospital settings in Knoxville and at the Davidson County Health Department were established in the late 1930’s.
- **1950’s** Oral contraceptives became available, although they were generally limited to clients of private physicians in the late 1950’s.
- **1963** A family planning clinic opened to the public in Oak Ridge by the Planned Parenthood Federation, using space furnished by the Department of Public Health. In November, the Tennessee Public Health Council approved Family Planning as a Public Health program.
- **1964** In January, the first Public Health Family Planning clinic opened in Williamson County.
- **1965** Two firsts occurred: (a) Metropolitan Nashville-Davidson County Health Department opened a clinic using federal funds for family planning. This was the first clinic in Region IV and the third clinic in the nation to use federal funds for family planning. (b) Tennessee Department of Public Health published the first Family Planning brochure.
  - Family planning services now were available in three counties.
- **1967** In February, Tennessee Department of Public Health endorsed statewide public funded Family Planning and in June, there was a budget expansion request for family planning.
- **1968** A survey showed that 93.4 percent of women in need of subsidized family planning were unable to obtain it.
  - At this point, the number of counties providing family planning services had increased from 3 to 83.
  - Family Health Services wrote a formal proposal for an \$800,000 family planning project in the five Southwest counties with the highest infant mortality rates.
- **1969** The first federally funded rural family planning project was established in five Southwest counties.

- **1970** The first Tennessee State Director of Family Planning was hired. A computerized data system, the Family Planning Mainframe, was developed and used. During the late '70s, the state Family Planning Program (FPP) contracted with Cytology Screening Laboratories, Albany, New York, to provide reading of Pap smears.
- **1971** Federal Title X-enabling legislation passed with the first categorical family planning dollars.
  - The Tennessee Family Planning Act was passed.
  - The first Tennessee Title X family planning grant was submitted with a total budget of one million dollars.
  - Publicly supported family planning was available to residents in all 95 counties.
- **1972** A grant award was received for \$900,000, the first Title X money to support family planning clinics in Tennessee.
  - The State Family Planning Advisory Council was established, and regional council organization was begun, with all nine functional by
- **1973** The first Family Planning Nurse Practitioners (FNP's) were trained, and the team concept was established.
  - Within two years, ten FNP-headed teams served clients in 50 counties.
  - The Certified Nurse Midwife (CNM) classification was established in Tennessee, and the first CNM was hired.
- **1974** Title IV-A (subsequently known as Title XX program) funds became available for family planning. Regional Family Planning Administrator positions were established.
  - By the end of the year, the regionalization of the FPP was complete. Title X funds totaled \$1.5 million.
- **1975** Special project funds from Title V (MCH) were awarded for a teen clinic in Nashville.
- **1976** The family planning client load peaked at 163,000.
- **1977** The sliding fee scale for family planning services was established, and fee collections were begun. Before this time, no charges were ever made to clients using the Family Planning clinics statewide.
- **1978** A Teen Initiative Project was begun with special Title X funds. From 1978- to 1979, the total family planning budget was \$8.8 million from 7 different sources: Title V, Title X, Title XIX, Title XX, state appropriations, local match, and client fees.
- **1979** The FPP was merged into the Maternal and Child Health Division.
- **1982** AIDS reporting in Tennessee begins (HIV reporting began in 1992).

- **1992** In February, the Norplant system became available to clinics.
- **1993** In August, Depo-Provera became available to clinics.
- **1994** The TennCare Program was established, which significantly impacted the FPP. Screening of family planning clients for Chlamydia was instituted.
  - Emergency contraception was approved for use in Family Planning clinics in Tennessee.
- **1995** Family planning services were available at 142 clinic sites in all 95 counties. There were 96,201 unduplicated contraceptive clients.
- **2010** The Affordable Care Act law for comprehensive health care reform was enacted in March 2010.
- **2013** Tennessee made Neonatal Abstinence Syndrome a Reportable Disease. This addition allowed real-time data about NAS incidence and helped inform efforts aimed at the primary prevention of NAS.
- **2016** Outbreaks of Zika and increased reports of congenital disabilities, and Guillain-Barré syndrome in areas affected by Zika.
  - The World Health Organization (WHO) declared a Public Health Emergency of International Concern (PHEIC) because of Zika.
  - The first case of Zika virus disease in Tennessee.
  - Tennessee State Legislature approves a bill to provide easier access to birth control by allowing women 18 or older to obtain contraceptives directly from pharmacists.
- **2017** TennCare MCOs agree to implement a billing policy change to allow TennCare enrollees who would choose a LARC contraceptive option to have access to their device of choice immediately following delivery during an inpatient stay.
- **2019** Department of Health and Human Services issues the 2019 final rule to revise the Title X family planning program regulations. The 2019 regulation focuses on compliance with the underlying Title X statute.
  - It clarified between permissible Title X activities and impermissible ones by requiring clear financial and physical separation for Title funded-funded programs from programs and facilities where abortion is a method of family planning.
- **2020 COVID-19 Pandemic Response**
  - Tennessee Family Planning Services were directly impacted by the Novel Coronavirus (COVID-19). On Thursday, March 12, 2020, Governor Bill Lee issued Executive Order No. 14 declaring a state of emergency in Tennessee to facilitate the treatment and containment of COVID-19.



- All TFPP sites remained dedicated to ensuring family planning client needs were met while leading the public health response to the COVID-19 pandemic. In Tennessee, family planning methods and services provided to help clients either prevent pregnancy or achieve pregnancy are considered essential healthcare services. Family planning providers continue to meet clients' needs while keeping themselves and clients safe during this nationwide COVID-19 public health emergency.
- Telehealth - TFPP had begun exploring telehealth as a service option when the COVID-19 pandemic struck. To mitigate the spread of COVID-19 while simultaneously providing services for clients who may be affected, TFPP began a telehealth program. Workflows, protocols, and policies that enabled TDH to offer various telehealth options, including phone calls, video calls, and chats, were established. TFPP started offering telehealth visits, and both clients and staff quickly embraced telehealth.
- **50 years of Title X.**
  - For 50 years, Tennessee Family Planning Program celebrates 50 years of Family Planning services. Tennessee is proud to have been a Title X grantee since the inception of the National Family Planning Program.
- **2021 Title X Final Rule**
  - On October 4, 2021, the U.S. Department of Health and Human Services (HHS) Office of Population Affairs (OPA) amended the Title X Family Planning regulations to restore access to *equitable, affordable, client-centered, quality family planning services* for more Americans.
  - The 2021 regulations reinforce the program's central tenets of quality, equity, and dignity for all individuals who seek Title X services and modernize the more than 50-year-old program to reflect the current healthcare system better.

**2022** Administratively, the Central Office Family Planning Program (FPP) personnel oversee the program for the entire state. The Central Office staff consists of the FPP Director, the Women's Health Clinical Trainer, Reproductive Women's Health Epidemiologist, and the Financial Administrator. Each region and each contracting agency appoint a Family Planning Administrator (FPA) who receives and disseminates information to their region, is responsible for the development of the annual Title X work plan and progress report for their region and performs a multitude of other duties as described in this manual.

The TFPP currently oversees Title X services in every county health department in Tennessee. The program leads efforts with interdisciplinary teams of health care professionals from a broad range of fields including obstetrics and gynecology, public health, nursing, epidemiology, social work, health education, and fiscal administration. Furthermore, the program draws on expertise statewide from those serving in the institutional and private reproductive health sectors to make the program as technically strong and as a community oriented as possible. Many changes have occurred since the first few traveling family planning teams started in 1972. Much progress in technology has occurred, and many lessons have been learned.

Today, even though there is diversity across the state system as to how the traditional services of family planning are provided (some have integrated clients into women's health clinics or primary care clinics; some continue the conventional family planning clinic sites), one thing has not changed: As in the earliest days, the goal of the TFPP is to provide quality services to low-income, high-risk individuals in need of health care.

The Public Health Service Act authorizes the Family Planning/Title X Program through the Family Planning Services and Population Research Act of 1970. This Act established the Office of Population Affairs (OPA), within the U.S. Department of Health and Human Services (HHS), to manage the Title X grant program, including family planning services and population research. For more than 50 years, Title X family planning clinics have played a critical role in ensuring access to a broad range of family planning and preventive health services, including breast and cervical cancer screening and STI/HIV testing. The program is implemented through competitively awarded grants to state and local public health departments, community health, family planning, and other private nonprofit agencies.

Title X projects may also include other reproductive health and related preventive health services that are considered beneficial to reproductive health, such as HPV vaccination, provision of HIV pre-exposure prophylaxis (PrEP), breast and cervical cancer screening, and screening for obesity, smoking, drug, and alcohol use, mental health, and intimate partner violence. By law, Title X funds may not be used in programs where abortion is a method of family planning. For many clients, Title X providers are their only ongoing source of health care and health education. All Title X service sites provide quality healthcare that is safe, effective, client-centered, timely, efficient, and equitable.

Title X core services include contraceptive services, pregnancy testing, and counseling, optimal family spacing, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, preconception health, preventive health services, and adolescent-friendly health services. Family planning services are provided in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.

Title X is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. Family planning clinics have played a critical role in ensuring access to these services for millions of low-income or uninsured individuals and other vulnerable populations. President Nixon signed the Title X Bill in 1969, which states “No American woman should be denied access to family planning assistance because of her economic condition.”

## TITLE X PROGRAM PRIORITIES

OPA establishes program priorities that represent overarching goals for the Title X program. Program priorities derive from the HHS priorities. Tennessee Family Planning Program project plans are developed to address the OPA designated Title X program priorities.

Title X Priorities include all the legal requirements covered within the Title X statute, regulations, and legislative mandates. All sub-recipients must comply with the requirements regarding the provision of family planning services according to Title X of the Public Health Service Act, 42 U.S.C. § 300 et seq., and the implementing regulations. Legislative mandates and the 2021 Final Rule:

<https://www.federalregister.gov/documents/2021/10/07/2021-21542/ensuring-access-to-equitable-affordable-client-centered-quality-family-planning-services>

The Tennessee Department of Health, as the sole Tennessee Title X grantee, allocates awarded federal Title X funds first to local health departments and contracted Metro Health Departments. TFPP providers are committed to providing quality family planning services in their area and the state. Metro Health Department allocations are determined annually based on a formula that includes the availability of funds, the number of unduplicated family planning clients seen in the previous calendar year, and the extent of the Metro's family planning services. All metros and non-health department clinic services are reimbursed through a fee for services methodology.

There are several options for purchasing Family Planning products supplied to the Tennessee Department of Health clinics. The majority of the contraceptives provided are purchased through a State contract with a single wholesaler/distributor selected by the State using a standard competitive bid process. As a Title X TFPP participant, the State of Tennessee is eligible for Public Health Service (PHS)/340B pricing. The wholesaler provides manufacturer contracted 340B pricing for all Family Planning products. The State is also a member of the 340B Prime Vendor Program, that is available through a contract issued by the federal government. The Prime Vendor Program allows the State to acquire prices below PHS pricing for additional savings and improves access to some Family Planning products.

Pregnancy test kits are screened for accuracy, reliability, and ease of use by a team of nurses and laboratory staff at the State laboratory facility. After being screened, the kits are purchased through a competitive bid process. Only pregnancy test kits approved through the screening are allowed to be included in the bid process. Metropolitan regions and non-profit agencies included in the Title X Program may use the State contracts or use procedures established by the agency for product purchasing.

## FAMILY PLANNING ANNUAL REPORT

The Family Planning Annual Report (FPAR) National Summary aims to present national, regional, and state-level findings for the calendar year and trends for selected measures: <https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report>. Annual submission of FPAR data to OPA is required by all Title X family planning services grantees authorized and funded under the Population Research and Voluntary Family Planning Programs (Section 1001 of Title X of the Public Health Service Act, 42 United States Code [USC] 300; 42 CFR Part 59) for purposes of monitoring and reporting program performance.

Information from the FPAR is important to OPA for several reasons:

- FPAR data monitors compliance with [statutory requirements, regulations, and operational guidance](#).
- OPA uses FPAR data to comply with accountability and federal performance requirements for Title X family planning funds as required by the 1993 Government Performance and Results Act (GPRA).
- The program relies on FPAR data to monitor performance, guide strategic and financial planning, and respond to policymakers and congressional inquiries about the program.

All TFPP service sites are required to capture patient-level FP encounter data. The method of data capture can vary by location, but ultimately the data for each service site is compiled by the RWH Epidemiologist who is responsible for preparing annual FPAR data, and approved by the FP Program Director. The FP Program Director ensures submission of these data to OPA by February 15<sup>th</sup> of each year. Each annual submission includes data for clients and encounters occurring during the previous calendar year (January 1 to December 31). Further details on FPAR can be found here: <https://opa.hhs.gov/research-evaluation/title-x-services-research/family-planning-annual-report>



## TITLE X CLINICAL REQUIREMENTS

Regardless of the extent of family services provided, Title X (42 CFR 59) subrecipients must adhere to all clinical requirements.

### GENERAL REQUIREMENTS

1. Family planning services must be voluntary and offered in a competent, non-discriminatory, trauma-informed manner, respecting client confidentiality. Services should ensure equitable and quality service delivery consistent with nationally recognized standards of care.
2. Family planning services must be provided without subjecting individuals to any coercion to accept services or to employ or not employ any particular methods of family planning. Any agency that is found to coerce or try to coerce any person may be fined or subject to prosecution.
3. Family planning services must be client-centered care respectful of and responsive to individual client preferences, needs, and values. Client values should guide all clinical decisions.
4. Family planning services must be inclusive and demonstrate health equity by providing services without regard to religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, social position, number of pregnancies, or marital status. Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse clients. Family planning services must be provided without the imposition of durational residency or a requirement that a physician refer the client.
5. Title X clinics must have written policies consistent with the HHS Office for Civil Rights policy.
6. Subrecipients may not provide abortion as a method of family planning.
7. Subrecipients should provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs, who are in close physical proximity to the Title X site, when feasible, to promote access to services and provide a seamless continuum of care.

8. Subrecipients must provide adolescent-friendly health services. They must encourage family participation in a minor's decision to seek family planning services. Concerning each minor client, ensure that the records-maintained document the action is taken to encourage such family participation or the specific reason why family participation was not encouraged.

## PERSONNEL REQUIREMENTS

**Family Planning Providers(s):** A family planning provider is an individual who assumes primary responsibility for assessing a client and documenting services in the client record. Providers include those agency staff that exercise independent judgment as to the services rendered to the client during an encounter. Family planning medical services will be performed under the direction of a clinical services provider, with services offered within their scope of practice and allowable under state law, and with special training or experience in family planning. Two general types of providers deliver Title X family planning services: advanced practice providers and other services providers.

**Advance Practice Providers** – A medical professional who receives a graduate-level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel clients (42 CFR Part 59.2). Advance practice providers are physicians, physician assistants, nurse practitioners, and certified nurse midwives, who are trained and permitted by state-specific regulations to perform all aspects of the client's physical assessments recommended for contraceptive, related preventive health, and basic infertility care. Advance practice providers should offer client education, counseling, referral, follow-up, and clinical services (physical assessment, treatment, and management) relating to a client's proposed or adopted method of contraception, general reproductive health, or infertility treatment.

**Other Service Providers** – Include other agency staff that provides any level of service to family planning clients. This includes registered nurses (RNs), licensed practical nurses (LPNs), certified nurse assistants, health educators, and social workers.

Any adequately trained service provider may perform the following duties:

- Obtain samples for routine lab tests (e.g., urine, pregnancy, sexually transmitted infection (STI), cholesterol, and lipid analysis).

- Perform routine clinical procedures that may include aspects of the client's physical assessment (blood pressure evaluation).
- Client education, contraceptive counseling, pregnancy counseling, preconception health counseling, referral, or follow-up services relating to the client's proposed or adopted method of contraception, general reproductive health, and basic infertility counseling.

The following duties must be performed by an advanced practice provider, RN, or LPN:

- Provide contraceptive injections (Dep-Provera) and provide contraceptive methods to a client as ordered.

The TFPP maintains approved personnel policies and procedures. TDH has established and maintains personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language. These policies include, but are not limited to, staff recruitment, selection, performance evaluation, promotion, termination, compensation, benefits, and grievance procedures. [Policies by Category \(tn.gov\)](#)

- TFPP staff are broadly representative of all significant elements of the population served by the FPP and are sensitive to and able to deal effectively with the cultural and other characteristics of the FPP client population.
- A qualified project director administers the TFPP. Any change in status, including the absence of the project director and other key personnel are pre-approved by the Office of Grants Management.
- TFPP medical services are performed under the direction of a physician with special training or experience in family planning.
- Appropriate salary limits will apply as required by law.

## MEDICATION GUIDELINES

Each TFPP site has established and maintains a medication policy and guidelines for all staff to follow. These guidelines are written and developed following state and federal requirements.

Client education and counseling should be client centered. Provide all education and counseling in a culturally competent manner to meet the needs of all clients regardless of religion, color, national origin, disability, age, sex, sex characteristics, gender identity, race, sexual orientation, number of pregnancies or marital status. All clients must have a reproductive life plan assessment, which outlines personal goals about achieving or avoiding pregnancy. Assessment of reproductive life plan may identify unmet reproductive health care needs. The American College of Obstetricians and Gynecologists (ACOG) strongly supports access to comprehensive and culturally appropriate reproductive life planning. It encourages providers to use every client encounter as an opportunity to talk with clients about their pregnancy intentions. If the client indicates that they prefer to have a child at a time in the future and is sexually active with no use of contraceptives, offer contraceptive services. Also, offer the *Family Planning It's More Than You Think* brochure. [Family Planning - Family Planning is More Than You Think Brochure English.pdf - Folders \(sharepoint.com\)](#), [Family Planning - Family Planning Is More Than You Think Brochure - Spanish.pdf - Folders \(sharepoint.com\)](#), or [Family Planning - Family Planning Is More Than You Think Brochure-ARABIC.pdf - Folders \(sharepoint.com\)](#).

If the client is not pregnant and indicates the desire to have a child now, then provide appropriate services and counseling or refer for services to help the client achieve pregnancy [2.105 Preconception Health Services.pdf](#).

When initiating a new method of contraception, help the client develop a plan for appropriate use, provide the desired contraceptive, followed with instructions for correct and consistent use, and document client understanding. Provide a follow-up appointment if indicated or if client understanding is not confirmed. Certain consents are only required for the following family planning methods and procedures:

- IUD Insertion and Removal, [Family Planning - Liletta Consent 6-yr.pdf - Folders \(sharepoint.com\)](#), [Family Planning - Nexplanon consent English 2021.pdf - Folders \(sharepoint.com\)](#)
- Contraceptive Implant Insertion and Removal, and [Family Planning - TDH Procedure Consent form PH 3914.pdf - Folders \(sharepoint.com\)](#)
- Sterilization Consent. [Family Planning - consent-for-sterilization-English-updated expires 2022.pdf - Folders \(sharepoint.com\)](#)

- All consent forms are available in English and Spanish. [Family Planning - GENERAL CONSENT FOR HEALTH SERVICES.pdf - Folders \(sharepoint.com\)](#)

## ADOLESCENT CONSENTS AND COUNSELING

Adolescents may consent to family planning services without the consent of a parent.

[Family Planning - Mature Minor Doctrine.pdf - Folders \(sharepoint.com\)](#) All

adolescents must be counseled:

- Sexual abstinence is an effective way to prevent pregnancy and STIs,
- How to resist being coerced into engaging in sexual activities and encourage the minor to involve their family (including guardians) in their decision to seek family planning services. However, Title X projects may not require the consent of parents or guardians for the provision of services to minors, nor can any Title X project staff notify a parent or guardian before or after a minor has requested and received Title X family planning services.
- Documentation on adolescent counseling must be noted in the medical record. Likewise, documentation should indicate the reason(s) why counseling was not provided.

## PREGNANCY COUNSELING (42 CFR PART 59.5)

Title X funds are intended only for family planning (achieving or avoiding pregnancy).

Confirmation that a family planning client is pregnant should prompt a referral to a healthcare provider for prenatal care and, if eligible, referral for *TennCare* Presumptive

<https://www.tn.gov/health/health-program-areas/fhw/rwh/tenncare-presumptive-eligibility/>.

- Prenatal presumptive eligibility (PE) is a *TennCare* Medicaid coverage category for pregnant individuals. The presumptive eligibility option encourages early entry into prenatal care for improved health outcomes for the mother and the baby. A pregnant woman who qualifies for presumptive eligibility can begin receiving covered services when she is approved for PE. The intent is to offer prenatal care at the earliest possible time during pregnancy. Presumptive eligibility gives the pregnant individual *TennCare* coverage through the end of the month following the month of approval to allow time to apply for regular Medicaid. Both the PE and full Medicaid applications are completed at local health departments.

Adequately trained TFPP staff providing family planning services to a client may provide information and counseling to a pregnant client as follows:

- Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:
  - Prenatal care and delivery
  - Infant care, foster care, or adoption; and
  - Pregnancy termination - if requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except concerning any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

Any licensed clinic staff may provide the following information and resources:

- A list of licensed, qualified comprehensive primary health care providers, including prenatal care providers; [Family Planning - Resource Lists - Community and Provider - Folders \(sharepoint.com\)](#)
- A list and referral to social services, community agencies, and/or adoption agencies; [Family Planning - Resource Lists - Community and Provider - Folders \(sharepoint.com\)](#)
- Information about maintaining the health of the mother and unborn child during pregnancy. [CHS/CLS/NURS - 2.110 Pregnancy Test 02012022 signed.pdf - Folders \(sharepoint.com\)](#)

## MANDATORY REPORTING REQUIREMENTS

Title X subrecipients shall comply with all state and local mandatory reporting laws requiring notification of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. A subrecipient must have a plan that can be implemented. The plan should include the following:

- Policies and procedures that address obligations of the organization and individuals to comply with mandatory reporting laws.
  - TFPP Policy & Procedure: [Mandatory Child Abuse Reporting 2022.docx \(sharepoint.com\)](#), TDH Policy & Procedure: [Family Planning - GM 3.06 Reporting of Child Abuse \(1\).pdf - Folders \(sharepoint.com\)](#),
- Adequate annual training of all individuals serving clients.
  - The TFPP requires mandatory routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation,



sexual abuse, rape or incest, intimate partner violence, cultural competency, and human trafficking. This training is provided initially during orientation and annually after that for all TFPP staff.

- Mandatory Reporting training includes using the Tennessee Department of Children Services (DCS) "Child Abuse Reporting" presentation found on the DCS website. The presentation can be found at:  
<https://www.tn.gov/content/tn/dcs/program-areas/training/cw-resources/mandated-reporter-training.html>
- Documentation in the medical record of the age of a minor client and the age of the minor client's partner.
  - The Abuse and Neglect Report, PH-2947, will be used for documenting suspected abuse. Completing PH-2947 will be documented in the medical record if the victim is a health department client. [Family Planning - Abuse and or Neglect Report\(PH-2947\).pdf - Folders \(sharepoint.com\)](#) The original copy of the PH-2947 will be maintained in a confidential file separate from the client's health record in the health department clinic. A copy of the PH-2947 Form will be sent, marked CONFIDENTIAL, to the Regional Nursing Director. Permission will not be needed to report the suspected abuse. In most circumstances, the employee's supervisor will be consulted before submission of a report. If such consultation is not available, the supervisor will be notified following the submission of a report.
- Screening for abuse, neglect, and victimization of all clients, especially adolescent/minor clients.

## CONFIDENTIALITY

All information about personal facts and circumstances obtained by the TFPP staff about individuals receiving services must be held confidential. Only information necessary to provide services to the client or as required by law may be disclosed without documented consent. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. TFPP staff inform the client of any potential for disclosing their confidential health information to policyholders where the policyholder is someone other than the client. Confidentiality of data will not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws (42 CFR Part 59.10).

- TFPP clients may request an extra layer of confidentiality because of personal circumstances. TFPP clinics have a mechanism in place in the health record and other documentation to identify these clients and ensure that no communication will be sent to the home of a confidential client, including billing statements, payer explanation of benefits regarding the visit, lab results, etc.
- Eligibility for discounts for unemancipated minors seeking or receiving confidential services in the Title X Project is based solely on the adolescent's resources. TFPP Policy & Procedure-[Discount Eligibility for Minors 2022.docx \(sharepoint.com\)](#), [Family Planning - CHS-4.8 Confidential Services Policy.pdf - Folders \(sharepoint.com\)](#)
- Income and sliding scale fees shall be assessed on a confidential client based on the individual's income, not household income. Inability to pay shall not be a barrier to treatment, and a billing statement or other communication should never be sent to the client's home. These clients may be treated as uninsured, regardless of their insurance status, and the Family Planning Program may be invoiced for their services. Eligibility for discounts for unemancipated minors seeking or receiving confidential services in the Title X Project is based solely on the adolescent's resources. TFPP Policy & Procedure-[Discount Eligibility for Minors 2022.docx \(sharepoint.com\)](#), [Family Planning - CHS-4.8 Confidential Services Policy.pdf - Folders \(sharepoint.com\)](#)

## INFORMATION & EDUCATION ADVISORY COMMITTEE AND MATERIAL APPROVAL

Each TFPP region/metro/agency is required to have an Information and Education Advisory Committee (I & E Committee) review and approve all informational and educational (I & E) materials (print and electronic) developed or made available under the TFPP before distributing them. The TFPP shall not disseminate any materials not approved by the Advisory Committee.

- The I & E materials review process ensures that materials developed or made available under the project are suitable for the intended population or community. All materials that TFPP disseminate must go through this process. The I & E materials review process is mandated through the Code of Federal Regulations (CFR 59.6) [eCFR:: 42 CFR Part 59 Subpart A -- Project Grants for Family Planning Services](#), which specifies that materials must be reviewed by the Advisory Committee of at least five individuals who broadly represent the population or community for whom the materials are intended. The Committee

members review the materials to ensure they reflect the intended population or community's educational, cultural, and diverse backgrounds. For further information, see Information & Educational Advisory Committee, and Community Participation, Education, and Project Promotion Plan Reference Page.

## TRAINING REQUIREMENTS FOR FAMILY PLANNING STAFF

All staff involved in Family Planning are required to complete annual training on specific Family Planning policies and procedures, including:

- Family Planning Policies and Procedures
- Title X Requirements and Priority Areas
- Mandatory Reporting (Child Abuse)
- Intimate Partner Violence
- Human Trafficking
- Cultural Competency
- Sexual coercion avoidance education for adolescents

The TFPF training plan is updated annually in January. The training plan is located in *Sharepoint*: [Training Plan Title X 2022.docx \(sharepoint.com\)](#)

- Specific training verification forms are used, by the FPA, to report completed trainings to Central Office program staff. Semi-annual Reports are uploaded into *Sharepoint* [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Central Office Family Planning Program staff monitors training records uploaded into Sharepoint to ensure compliance with this requirement and that all guidelines are met
- Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant cycle.

## BILLING AND COLLECTION

Title X clients are to be billed according to a sliding fee scale, based on family/household income, using the sliding fee schedule adopted by the organization (e.g., National Health Service Corps (NHSC) Sliding Fee Schedule, Uniform Percentage Guideline Scale) [Family Planning - Sliding Fee Scale & FPL - Folders](#)

[\(sharepoint.com\)](#).. This schedule ensures discounts for individuals with family incomes based on a sliding fee scale between 100–250% of poverty.

- Clients receiving only family planning services and are 100% below the federal poverty level (FPL) may not be charged, including a nominal fee. [Family Planning - CHS-4.17 Sliding Scale Schedule of Discounts Policy.pdf - Folders \(sharepoint.com\)](#)

Additional billing guidelines:

- Ensure that inability to pay is not a barrier to services.
- Be based on a cost analysis of services; bills showing total charges shall be given directly to the client or another payment source.
- Ensure that discounts for minors requesting confidential services without the involvement of a principal family member are based only on the income of the minor.
- Household income should be assessed before determining whether copayments of additional fees are charged. Regarding insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.
- Clients without adequate contraceptive services coverage from employer-paid insurance should be treated as uninsured for the TFPP services.
- Maintain reasonable efforts to collect charges without jeopardizing client confidentiality (*see Confidentiality section*).
  - All clients are asked to provide their household income and family size at every visit, to ensure at least annually assessment of changes in income. [Family Planning - CHS-4.17 Sliding Scale Schedule of Discounts Policy.pdf - Folders \(sharepoint.com\)](#)
- Allow voluntary donations. [Voluntary Donations 2022.docx \(sharepoint.com\)](#)
- Ensure that client income is re-evaluated at least annually and maintain a method for “aging” outstanding accounts. [Family Planning - CHS-4.1.c Private Pay Write Off Policy.pdf - Folders \(sharepoint.com\)](#)

## CONTRACEPTIVE SERVICES

TFPP contraceptive services include a broad range of FDA-approved contraceptive methods, a brief assessment to identify safe contraceptive methods for the client, and contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently. All TFPP clinic sites provide and stock a variety of the most effective contraceptive methods, including, but not limited to, IUD, hormonal implant, Depo-Provera, oral contraceptives, emergency contraception, hormonal patch, and the contraceptive vaginal ring should be available either on-site or by referral with a contracted provider. Uninsured clients 100% below the federal poverty level must not be required to pay for a contraceptive method. Uninsured clients should receive the desired method without a cost to the client. Condoms are made available to all clients for contraception and STI prevention.

Contraceptive counseling and education should be provided to all clients. They should include information on non-hormonal contraception, including, but not limited to, condoms, fertility awareness-based methods, and sexual risk avoidance/abstinence. Education is an essential component of the contraceptive counseling process that helps clients make informed decisions and obtain the information they need to use contraceptive methods correctly.

TFPP service providers utilize PATH, Family Planning - PATH - Folders ([sharepoint.com](https://sharepoint.com)), to assess a client's reproductive life goals. The PATH questions are a client-centered approach to assessing Parenthood/Pregnancy Attitude, Timing, and How important is pregnancy prevention.

- PATH can be used with clients of any gender, sexual orientation, or age.
- PATH is designed to facilitate listening and efficient client-centered conversations about preconception care, contraception, and fertility.

## STERILIZATION

Sterilization is a TFPP service that may be provided or arranged for with state government funding. To provide sterilization, federal sterilization consent guidelines must be followed. [Family Planning - Sterilization consents-OPA - Folders \(sharepoint.com\)](#). Medicaid and *TennCare* also have the same requirements as Title X. In Tennessee, program funding for sterilization is limited.

- TFPP clinic sites should keep a list of clients requesting sterilization through the state sterilization program, [Sterilization Report Blank.doc \(sharepoint.com\)](#) and prioritize applicants when funds for sterilization are available.

- For detailed information on policy, federal sterilization requirements, selection criteria, sterilization consent forms, and general instructions access the Office of
- Population Affairs website at <http://www.hhs.gov/opa/pdfs/42-cfr-50-c.pdf>

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## CONTRACEPTIVE FOLLOW UP

Contraceptive follow-up is at the discretion of the TFPP provider. The following follow-up appointment routines are suggested but not mandated:

- IUD Insertion: Return in 4-6 weeks for evaluation, then annually.
- Depo-Provera Users: Return in 11 to 13 weeks for the next injection.
  - Counsel on receiving injections on time.
  - Special considerations that may require a scheduled follow-up visit:
    - Clients with a history of inconsistent or incorrect use of a method.
    - Clients who have had problems with other contraceptive methods.
    - Clients fitted with a diaphragm may need a follow-up visit to ensure the client is appropriately placing the device.
- Routine follow-up visits are not required for most clients utilizing other contraceptive methods. Clients should be advised to return to discuss questions regarding their contraceptive choice, including complications and barriers to compliance with the method.
- Alternative modes of follow-up, other than in-person visits to the service site, may be utilized. These include Telehealth, telephone call, e-mail, or text message, with the client's request/consent.

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## PREGNANCY TESTING AND COUNSELING

Pregnancy testing and counseling are a fundamental TFPP service. Counseling clients with negative pregnancy results include these services:

- **Actively seeking pregnancy**
  - Preconception Health Services (PHN Protocol 2.105)
  - Fertility Awareness Based Methods (PHN Protocol 2.090)
  - Basic Infertility Counseling (PHN Protocol 2.011)
  - Encourage evaluation by PCP or provider
- **Not actively seeking pregnancy or not actively preventing pregnancy**
  - Provide contraceptive counseling if requested
  - Offer Same Day Start as requested \
  - Offer Same Day Insertion and referral for LARC (if requested and available)
  - Offer ECP or ECP prescription as requested
  - Discuss preconception health, including folic acid



Counseling clients with positive pregnancy test results include opportunity to discuss prenatal care and delivery, adoption care, foster care, or infant care; and pregnancy termination may be discussed (if requested, should provide neutral, factual, non-directive counseling on each of the options), and provide referral upon request with the exception to any options which the pregnant client indicates they do not wish to receive such information and counseling. *See Pregnancy Counseling*

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## SEXUALLY TRANSMITTED INFECTION SERVICES

All TFPP clinic sites offer sexually transmitted infection testing and treatment. Services are provided per CDC's STI treatment and HIV testing guidelines. [Family Planning - Providing Quality Sexually Transmitted Diseases Clinical Services, 2020.pdf - Folders \(sharepoint.com\)](#). TFPP STI services include assessment and screening.

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## ACHIEVING PREGNANCY AND BASIC INFERTILITY SERVICES

TFPP providers offer basic infertility care as part of core family planning services following the recommendations of professional medical organizations. See the CDC publication Providing Quality Family Planning Services:

[https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm?s\\_cid=rr6304a1\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm?s_cid=rr6304a1_w). All clients reporting difficulty achieving pregnancy should be referred to an appropriate advanced practice provider for further evaluation and treatment.

- Both partners should be evaluated concurrently (recommendation of American Society for Reproductive Medicine, ASRM). The infertility clinic visit includes: a complete medical history, reproductive life plan, and sexual health assessment [2.011 Basic Infertility Services.pdf \(sharepoint.com\)](#)

Counseling provided during the visit is guided by information from the client during the medical and reproductive history and the physical exam findings. TFPP providers educate the client about how to maximize fertility.

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## PRECONCEPTION HEALTH SERVICES AND PREVENTIVE HEALTH SERVICES

TFFP sites provide preconception health services and related preventive health services to all family planning clients. Preconception describes any time an individual of reproductive potential is at risk of becoming pregnant or causing a pregnancy. TFFP preconception health-care services aim to identify and modify biomedical, behavioral, and social risks to health or pregnancy outcomes through prevention and management. It promotes the health of individuals of reproductive age before conception and thereby helps to reduce pregnancy-related adverse outcomes, such as low birth weight, premature birth, and infant mortality.

Preconception health includes a medical history screening and counseling for risks such as tobacco use, substance use, obesity, blood pressure, intimate partner violence, diabetes, immunizations, and depression. Related preventive health services include appropriate health screening and referral for treatment, including STI testing, cervical cancer screenings (Pap testing and HPV co-testing), clinical breast exams, mammograms.

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## LEGISLATIVE MANDATES

As amended by the [2021 Title X Final Rule](#) and its compliance dates, requirements regarding the provision of family planning services under Title X can be found in: Title X Statutes, Regulations, and Legislative Mandates <https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates>

Title X Statute - Five Major Provisions of the Law [Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. - PDF](#)

[Subpart A](#) - Project Grants for Family Planning Services

[Subpart C](#) - Grants for Family Planning Service Training

[Subpart B](#) - Sterilization of Persons in Federally Assisted Family Planning Projects

Title X of the Public Health Service Act authorizes the Secretary of Health and Human Services (HHS) to award grants for projects to provide family planning services to any person desiring such services, with priority given to individuals from low-income families.

Providing Quality Family Planning Services, Recommendations of CDC, and the U.S. Office of Population Affairs [Providing Quality Family Planning Services \(QFP\)](#) provides the standards of care and guidelines for all TFPP services.

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## CRITICAL ISSUES FOR TITLE X GRANTEES

While the requirements for Title X service grantees are derived from statutes, regulations, and legislative mandates, additional key issues represent overarching goals for the Title X program. These are determined based on priorities set by the Office of the Assistant Secretary of Health (OASH) and the Office of the Secretary (OS) of the Department of Health and Human Services (HHS). The key issues are as follows:

1. Assuring innovative quality family planning and related preventive health services that lead to improved reproductive health outcomes and overall optimal health, defined as a state of complete physical, mental, and social well-being and not merely the absence of disease. Guidance regarding the delivery of quality family planning services is spelled out in the April 25, 2014, MMWR, Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. Periodic updates have been made to this publication and are available on the Quality Family Planning page. It is expected that the core family planning services listed in the Program Description, which also are included in the Quality Family Planning Services document referenced above, will be provided by each project.
2. Providing the tools necessary for the inclusion of substance abuse disorder screening into family planning services offered by Title X applicants.
3. Following a model that promotes optimal health outcomes for the client (physical, mental, and social health) by emphasizing comprehensive primary health care services and family planning services, preferably in the same location or through nearby referral providers.
4. Providing resources that prioritize optimal health outcomes (physical, mental, and social health) for individuals and couples with the goal of healthy relationships and stable marriages as they make decisions about preventing or achieving pregnancy.
5. Providing counseling for adolescents that encourages sexual risk avoidance by delaying the onset of sexual activity as the healthiest choice and developing tools to communicate the public health benefit and protective factors for the sexual

health of adolescents found by delaying the onset of sexual activity, thereby reducing the overall number of lifetime sexual partners.

6. Communicating the growing body of information for a variety of fertility awareness-based methods of family planning and providing tools for applicants to use in client education about these methods.
7. Fostering interaction with the community and faith-based organizations to develop a network for client referrals when needs outside the scope of family planning are identified.
8. Accurately collecting and reporting data, such as the Family Planning Annual Report (FPAR), to monitor performance and improve family planning services.
9. Promoting the use of a standardized instrument, such as the OPA Program Review Tool, to regularly perform quality assurance and quality improvement activities with clearly defined administrative, clinical, and financial sub-recipients for applicants and subrecipients; and
10. Increasing attention to CDC screening recommendations for chlamydia and other STDs (and HIV testing) that have a potential long-term impact on fertility and pregnancy.

The Tennessee Family Planning Program and services are governed by § 68-34-101 of the Tennessee Code Annotated . This chapter of the TCA is known and may be cited as the “Family Planning Act of 1971.” [Family Planning - TCA Chapter 1200-16-01.20200420 Family Planning Rules 2020.pdf - Folders \(sharepoint.com\)](#)

## PROHIBITION OF ABORTION

Title X funds and TFPP funds are not used in programs where abortion is a method of family planning. By state law, T. C. A. § 9-4-5116, [Tenn. Code Ann. § 9-4-5116](#). No state funds shall be expended to perform abortions. The limitations established in this section shall not apply to an abortion if:

- (1) The pregnancy is the result of an act of rape or incest; or
- (2) In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless the abortion is performed.

As The TFPP is a Title X grantee, we are in full compliance with Section 1008 of the Title X statute and 42 CFR 59.5(a)(5), which prohibits abortion as a method of family planning. TFPP has written policies that indicate that none of the funds will be used in programs where abortion is a method of family planning.



The “mature minor” doctrine in Tennessee permits healthcare providers to treat certain minors without parental consent, according to the “*Rule of Sevens*” (See *Cardwell v. Bechtol*, 724 S.W.2d. 739 (Tenn. 1987)). [Family Planning - Mature Minor Doctrine.pdf - Folders \(sharepoint.com\)](#)

- Under the age of 7, there is no capacity, and the physician must have parental consent to treat (unless a statutory exception applies).
- Between the ages of 7 and 14, there is a rebuttable presumption that there is no capacity, and a physician generally should get parental consent before treating (unless a statutory exception applies).
- Between the ages of 14 and 18, there is a rebuttable presumption of capacity. The physician may treat without parental consent unless the physician believes that the minor is not sufficiently mature to make their own health care decisions.

Specific statutes also explicitly permit the treatment of minors for specific conditions without parental consent, including treatment of juvenile drug abusers (T.C.A § 63-6-220), emergency situations (T.C.A § 63-6-222), treatment for STDs (T.C.A § 68-10-104(c), providing contraception (T.C.A § 68-34-107) and providing prenatal care (T.C.A § 63-6-223). In the case of abortion, however, the legislature has made clear that no minor may obtain an abortion without either parental consent or a court order in exceptional circumstances.

Tennessee county health departments follow Tennessee law and provide medical treatment and vaccinations to clients as young as 14 without parental consent if the individual provider determines that the client meets the definition of a “*mature minor*” in accordance with Tennessee law.

*The Program Requirements for Title X Funded Family Planning Projects* [Family Planning - Title-X-2014-Program-Requirements \(2\).pdf - Folders \(sharepoint.com\)](#) provides the framework for family planning services. The Department of Health and Human Services (DHHS) and the Office of Population Affairs (OPA) require adherence to these guidelines. The OPA has divided the United States and its territories into ten federal regions. Tennessee is in Region IV. Each federal region is assigned the responsibility to ensure that all the states within its region comply with the Title X guidelines.

Each state is also assigned the responsibility of assuring all providers of Family Planning services within the state comply with the Title X guidelines. Compliance is evaluated through on-site program reviews. On-site visits generate data that form the basis for decisions and help Region IV, the Tennessee FPP, and regional/metro/agency offices take corrective action and identify program areas that require additional support. Moreover, data analysis can produce information about the needs of the providers of family planning services, information necessary for developing and carrying out responsive technical assistance, consultation, and training activities. Two types of on-site visits for the program review are described below:

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### FEDERAL SITE VISITS FOR PROGRAM REVIEW:

- Through the Project Officer, OPA staff schedule program reviews of the Title X Family Planning grantees generally every three years. The on-site visits review four primary areas: administrative, financial, clinical, and community participation. State family planning administrative offices, regional/metro offices, local health departments, and contract agencies are reviewed in federal site visits. The regional and local sites to be reviewed are rotated throughout the state. The federal team meets with key state staff to review records and manuals and discuss the program from the state perspective. The team then visits local health departments, regional offices, and contract agencies to evaluate the services in-depth. .

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### TENNESSEE ON-SITE CONTRACT MONITORING VISITS:

- The Department of Health requires state contracts be monitored through on-site visits at all contract agencies. In accordance with policies in the Family Health

and Wellness Division, all contract agencies are to be visited at least every three years. The FPP, therefore, has the responsibility for monitoring the family planning contracts. The visits are conducted by Central Office staff and are regularly scheduled, with additional attention and consultation being given when there are concerns or significant changes. Administrative, fiscal, clinical, educational, and outreach functions are reviewed and evaluated. Visits are scheduled through the Family Planning Administrator, responsible for notifying regional and local administrative staff and clinic site(s) as needed. A site review may include, but not be limited to, the following items:

- Organizational charts
- Client satisfaction survey results
- Nurse practitioner protocols
- Documentation that staff is aware of translation services policies and processes
- Manuals: Family planning program policy and procedures manual, Lab Manual, Family planning services clinical protocols, etc.
- Family planning client chart access at each service site, Minimum of 10 family planning medical records per site (some with abnormal Pap smears) for review
- Policy indicating prohibition of providing abortion as a method of family planning as part of the Title X project, Documentation that staff are prohibited from referring for abortion as part of the Title X project, except for medical emergencies, or in the case of rape or incest,
- Information on clients served
- Mechanism for follow-up on abnormal Pap smears or other medical problems
- Quality management audits/ semi-annual chart review reports
- Clinic coverage schedule, Clinic Hours
- Policy on how agency operationalizes cultural competency, Client bill of rights or other documentation which outlines client's rights and responsibilities, Non-discrimination policy
- Contract(s) with medical provider(s) and other family planning personnel if not on staff

- Documentation of medical provider licenses, prescriptive authority, and CPR certification, Licensed personnel list, Staff lab skills proficiency documentation, Abnormal laboratory results and follow-up documentation, Clinical Licenses
- Financial Policies, Records, Documents & Documentation
- Contract(s) with medical provider(s) and other family planning personnel if not on staff
- Staff training policy and plan, Evidence of staff training, Documentation that staff have been trained at least once during the current project period on permissible and impermissible Title X activities.
- Sample financial screening and eligibility determination forms and policy, Client billing and income verification records, Schedule of discounts and schedule of fees for clients at or below 250% of the federal poverty level
- Client flow observation
- HIPAA policy
- Resumes of family planning program director and medical director, Personnel policies, and procedures
- Referral list and written process used for required and recommended services not provided by agency. Written referral agreements and/or collaborative agreements with other health care and social service agencies
- Community participation, education, and promotion plan, Materials Review Committee information, Minutes from last information and education committee meeting, List of approved client education materials, Current list of information and education committee members(see appendix for forms and guidance. Forms are also available on Sharepoint at: [Family Planning - IE Committee Forms 2022 - Folders \(sharepoint.com\)](#))

Findings from site visits are documented in a written report to the contracted agency. This report includes areas to be commended, suggestions for improvements if needed, and any follow-up or required corrective action. A time frame is given for the contracted agency to respond with written corrective action documentation. A follow-up site visit may be necessary to monitor the contractor's corrective actions to assure that implementation resulted in the required improvements.

The TFPP is accountable for the quality, cost, accessibility, acceptability, reporting, and performance of the grant-funded activities provided.

- Where required services are provided by referral, the TFPP has written agreements for the provision of services and reimbursement of costs as appropriate. [Availability and Use of Referrals 2022.docx \(sharepoint.com\)](#)
- The TFPP ensures that all services purchased for the TFPP will be authorized by the project director or their designee on the project staff (42 CFR 59.5(b)(7)).
- The TFPP ensures that services provided through a contract or other similar arrangements are paid for under agreements that include a schedule of rates and payment procedures maintained by the TFPP. See Reimbursement Fee Schedule [FP Reimbursement rate 2021 CY FP Fee Schedule.xlsx \(sharepoint.com\)](#)
- The TFPP maintains a financial management system that meets federal standards, and any other requirements imposed by the Notice of Award, which complies with federal standards that will support effective control and accountability of funds. Documentation and records of all income and expenditures are maintained as required.

## CHARGES, BILLING & COLLECTIONS

The TFPP is responsible for implementing policies and procedures for charging, billing, and collecting funds for the services provided by the TFPP.

- Clients will not be denied project services or be subjected to any variation in the quality of services because of an inability to pay. [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)
- TFPP does not have a general policy of no fees or flat fees for providing services to minors or a schedule of fees for minors different from other populations receiving family planning services. [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)
- Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged. However TFPP shall bill all third parties authorized or legally obligated to pay for services. [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)
- TFPP relies on the client's self-report for income verification. [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)
- A schedule of discounts, based on the ability to pay, is available for individuals with family incomes between 101% and 250% of the FPL. [Family Planning - CHS-4.17 Sliding Scale Schedule of Discounts Policy.pdf - Folders \(sharepoint.com\)](#)
- Fees may be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services. [Family Planning - CHS Waiving Fees – 4.21 3.22.pdf - Folders \(sharepoint.com\)](#)
- For persons from families whose income exceeds 250% of the FPL, charges are made per a schedule of fees designed to recover the reasonable cost of providing services. [Reasonable Costs - Fee Schedules 2022.docx \(sharepoint.com\)](#)
- Eligibility for discounts for unemancipated minors who receive confidential services is based on the minor's income. [Discount Eligibility for Minors 2022.docx \(sharepoint.com\)](#)



- Where there is a legal obligation or authorization for third-party reimbursement, including public or private sources, TFPP makes all reasonable efforts to obtain third-party payment without any discounts. [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)
- The TFPP assesses family income before determining whether copayments or additional fees are charged. Regarding insured clients, clients whose family income is at or below 250% FPL should not pay more (in copayments or additional costs) than they would otherwise pay when the schedule of discounts is applied. [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)
- TFPP makes reasonable efforts to collect charges without jeopardizing client confidentiality. [Family Planning - CHS-4.8 Confidential Services Policy.pdf - Folders \(sharepoint.com\)](#)
- TFPP accepts voluntary donations from clients; however, clients are not pressured to make donations, and donations are not a prerequisite providing services or supplies. [Voluntary Donations 2022.docx \(sharepoint.com\)](#)

## STAFF TRAINING & TECHNICAL ASSISTANCE

The TFPP staff are responsible for the training of all FPP staff. [Staff Training and Project Technical Assistance 2022.docx \(sharepoint.com\)](#). The TFPP provides the orientation and in-service training of all FPP staff. This includes the staff of sub-recipient agencies and contracted service sites. The 2022 Family Planning Training Plan is available on Sharepoint: [Training Plan Title X 2022.docx \(sharepoint.com\)](#)

- Technical assistance is provided by the Office of Population Affairs (OPA), the Reproductive Health National Training Center (RHNTC) [Welcome to the Reproductive Health National Training Center | Reproductive Health National Training Center \(rhntc.org\)](#), the National Clinical Training Center for Family Planning (NCTCFP) [National Clinical Training Center for Family Planning – NCTCFP](#), Central Office and the Regional Office
- Annual staff training on specific policies and procedures is required. Key central office staff ensures TFPP staff are trained on the topics listed in this document at least once per project period unless otherwise specified. Other specific content requirements for each staff member shall be based on their roles and functions. [Family Planning - Federal Title X Training Requirements Summary.pdf - Folders \(sharepoint.com\)](#) Refer to the [Title X Statutes, Regulations, and Legislative Mandates | HHS Office of Population Affairs](#) for more information.
- The TFPP requires mandatory routine training of staff on Federal/State requirements for reporting or notification of child abuse, child molestation, sexual abuse, rape or incest, intimate partner violence, cultural competency, and human trafficking. This training is provided initially during orientation and annually for all TFPP staff.
- Mandatory Reporting training includes viewing of the Tennessee Department of Children Services' (DCS) "Child Abuse Reporting" presentation found on the DCS website. The presentation can be found at: <https://www.tn.gov/content/tn/dcs/program-areas/training/cw-resources/mandated-reporter-training.html>
- All staff who are involved in the TFPP are additionally required to complete the following training annually: Involving family members in the decision of minors to seek family planning services, counseling minors on how to resist being coerced into engaging in sexual activities, Family Planning Policies and Procedures, Title X Requirements and Priority Areas, Intimate Partner Violence, Human Trafficking, and Cultural Competency Training. Training links and attestation

forms are located as templates in Adobe Sign. [Family Planning - Annual Training Adobe - Folders \(sharepoint.com\)](#)

- Specific training verification forms are used to report completed trainings to Central Office FPP staff. Reports are uploaded into Sharepoint: [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Central office staff monitors these trainings to ensure compliance. Each TDH region/metro/agency keeps individual staff training documentation in their administrative offices and clinic sites.

Title X requires that grantees ensure that the project is competently and efficiently administered (42 CFR 59.5(b) (6) and (7)). To adequately plan and evaluate program activities, TFPP has developed written goals and objectives for the project period that are specific, measurable, achievable, relevant, time-bound, inclusive, equitable (SMARTIE), and which are consistent with Title X Program Requirements. The program plan is based on the state needs assessment. [Family Planning - Work Plans - Folders \(sharepoint.com\)](#). The TFPP project plans include an evaluation component that identifies indicators by which the program measures the achievement of its objectives. For more information on quality improvement, see Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. [Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs](#)

TFPP ensures that all persons who want to obtain family planning care have access to such services. The TFPP provides comprehensive medical, informational, educational, social, and referral services related to family planning for clients who want such services.

- Priority for TFPP services is to persons from low-income families. FPP services are provided in a manner that protects an individual's dignity. TFPP services are provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.
- The TFPP provides social services related to family planning including, counseling, referral to and from other social and medical services agencies, and any ancillary services necessary to facilitate clinic attendance.
- The TFPP provides coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs. The TFPP has a robust referral system and collaborates with community partners to meet clients' needs. [Family Planning - Collaborative Agreements and MOU's - Folders \(sharepoint.com\)](#), [Family Planning - 2022 Outside Providers - Folders \(sharepoint.com\)](#), [Family Planning - Resource Lists - Community and Provider - Folders \(sharepoint.com\)](#)

The TFPP ensures services operate within written clinical protocols in accordance with nationally recognized standards of care, approved by the TDH, and signed by the physician responsible for the service site [Family Planning - 2022 Family Planning Signature page & Clinical Guidelines.pdf - Folders \(sharepoint.com\)](#). The following resources have been reviewed and approved to serve as the Family Planning Clinical Guidelines:

- CDC. Providing Quality Family Planning (QFP) Services Recommendations of CDC and the U.S. Office of Population Affairs. MMWR 2014; 63 (No.RR-4). [Providing Quality Family Planning Services | Unintended Pregnancy | Reproductive Health | CDC](#)
- CDC. U.S. Medical Eligibility Criteria (USMEC) for Contraceptive Use 2016. MMWR 2016; Recommendations and Reports/Vol.65/No.3, July 29, 2016. [Update to U.S. Medical Eligibility Criteria for Contraceptive Use, 2016: Updated](#)

[Recommendations for the Use of Contraception Among Women at High Risk for HIV Infection | MMWR \(cdc.gov\)](#)

- CDC. U.S. Medical Eligibility Summary Chart 2020. [Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use. \(cdc.gov\)](#)
- CDC. U.S. Selected Practice Recommendations for Contraceptive Use 2016. MMWR 2016; 65 (No.RR-4). [U.S. Selected Practice Recommendations for Contraceptive Use, 2016 | MMWR \(cdc.gov\)](#)
- CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR 2021; Recommendations and Reports/Vol.70/No.4, July 23, 2021. [STI Treatment Guidelines \(cdc.gov\)](#)
- CDC. Preconception Health. [Overview | Preconception Care | CDC](#)
- CDC. How to Be Reasonably Certain That a Woman is Not Pregnant; When to Start Using Specific Contraceptive Methods; and Routine Follow-Up After Contraception Initiation. [How to Be Reasonably Certain That a Woman is Not Pregnant; When to Start Using Specific Contraceptive Methods; and Routine Follow-Up After Contraceptive Initiation. \(cdc.gov\)](#)
- CDC. Management of Bleeding Irregularities While Using Contraception & Management of IUC with Pelvic Inflammatory Disease (PID). [Management of Women with Bleeding Irregularities While Sing Contraception \(cdc.gov\)](#)
- CDC. Recommended Actions after Late or Missed Combined Oral Contraceptives(COCs). [Recommended Actions After Late or Missed Combined Oral Contraceptives \(cdc.gov\)](#)
- OPA. Contraception and Preventing Pregnancy. [Contraception and Preventing Pregnancy | HHS Office of Population Affairs](#)
- RHNTC. Birth Control Method Options. [Birth control methods chart \(rhntc.org\)](#)
- RHNTC. Explaining Contraception - Job Aids for Healthcare Providers. [RHNTC: Explaining Contraception Job Aids for Healthcare Providers \(English\).](#)
- Hatcher RA, Nelson AL, TrussellJ, Cwiak C, Cason P, Policar MS, Edelman A, Aiken ARA, Marrazzo J, Kowal D, eds. Contraceptive Technology. 21st ed. New York, NY: Ayer Company Publishers, Inc., 2018.
- Ziemann M, Hatcher RA, Allen A. Z. Managing Contraception 16th Edition 2021. Tiger, Georgia: Bridging the Gap Foundation, 2021.
- Perkins RB, Guido RS, Castle PE, Chelmow MH, Einstein MH, Garcia F, Huh WK, et. al. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Journal of Lower Genital Tract Disorders. Volume 24(2), 102-131. 2020
- The TFPP Family Planning Clinical Guidelines and resources are uploaded in *Sharepoint*: [Family Planning - 2022 Clinical Guidelines in PDF version - Folders](#)



[\(sharepoint.com\)](#) and paper copies are required at all TFPP clinic sites with an up to date signature page in the front of the guidelines.

The Offices of Nursing, Pharmacy, Oral Health, and the Medical Leadership Team provide guidance to regional, local, and metropolitan health departments to provide the best healthcare possible for the people of Tennessee. TDH provides specific provider protocols and nursing protocols [CHS/CLS/NURS - Nursing Protocols - Folders \(sharepoint.com\)](#).

- TFPP provides medical services related to family planning and the effective usage of contraceptive devices and practices (including physician's consultation, examination, prescription, continuing supervision, laboratory examination, and contraceptive supplies) as well as necessary referrals to other medical facilities when medically indicated. This includes but is not limited to emergencies that require referral.
- The TFPP provides a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and adolescents).
- TFPP services are provided without the imposition of any durational residency requirement or requirement that a physician refers the client. [Durational Residency 2022.docx \(sharepoint.com\)](#)
- The TFPP provides pregnancy diagnosis and counseling to all clients requesting this service. Pregnant individuals are offered the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery, infant care, foster care, adoption, and pregnancy termination. When such information and counseling are requested:
  - TFPP staff provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except for any options(s) about which the pregnant individual indicates she does not wish to receive such information and counseling.

## TELEHEALTH SERVICES

To increase community access, help ensure equitable access to essential care, and better meet the needs of family planning clients, the TFPP includes the provision of telehealth services. The guidelines for TFPP telehealth were developed using concepts of evidence-based practice and interdisciplinary collaboration throughout the State of Tennessee. The overall goal is to provide safe and quality care through telehealth services.

- Our policy, [Telehealth Policy and Procedure 2022.docx \(sharepoint.com\)](#), is to provide telehealth as an option for family planning service delivery to enhance access in convenient, safe, and equitable ways for our clients. Every effort was made to capture Tennessee's current policy language when it was reviewed. TN Code Annotated, Sec. 56-7-1002 & Sec. 56-7-1012, as amended by SB 2453 and HB 2655 (2022 session) (Accessed Apr.2022)
- <https://www.capitol.tn.gov/Bills/112/Bill/HB0620.pdf> and <https://www.capitol.tn.gov/Bills/112/Bill/HB2655.pdf>
- Family Planning Telehealth is available in all 95 counties in Tennessee. Telehealth services are convenient, confidential, culturally humble, HIPAA compliant, and readily available to all eligible TFPP clients. <https://www.familyplanningtn.com/>
- Other available Resources include:
  - *TDH Guide to Telemedicine* - [Family Planning - Telemedicine Manual.pdf - Folders \(sharepoint.com\)](#)
  - *Tennessee At A Glance – Tennessee State Telehealth Laws-CCHP* - [Family Planning - CCHP Tennessee Telehealth Laws Report, 05-10-2022.pdf - Folders \(sharepoint.com\)](#)
  - Work Up Flow Sheet - [Family Planning - Telehealth work up flow sheet DL.pdf - Folders \(sharepoint.com\)](#)
  - Contraception Initiation and management Flow sheet - [Family Planning - Telehealth Contraceptive Initiation & management workflow DL.pdf - Folders \(sharepoint.com\)](#)

## PRENATAL PRESUMPTIVE ELIGIBILITY

Prenatal presumptive eligibility (PE) is a TennCare Medicaid coverage category for pregnant individuals. The presumptive eligibility option encourages early entry into prenatal care for improved health outcomes for the mother and the baby. Pregnant individuals who qualify for presumptive eligibility can begin receiving covered services on the day that she is approved for PE. The intent is to offer prenatal care at the earliest possible time during pregnancy. Presumptive eligibility gives the pregnant individual TennCare coverage through the end of the month following the month of approval to allow time to apply for regular Medicaid. Both the PE and full Medicaid application are completed at local health departments.

The Tennessee Department of Health (TDH) is mandated by federal law to follow the Health Insurance Portability and Accountability Act (HIPAA). Additional Federal laws that fall under the general umbrella of HIPAA include the Health Information Technology for Economic and Clinical Health (HITECH) and the Genetic Information Nondiscrimination Act (GINA). The TFPP is obligated to respect and protect the privacy of records and information about clients who request or receive services at our FPP sites. See: HIPAA Policy Manual on SharePoint at: [Family Planning - TDH-HIPAA-Manual.pdf - Folders \(sharepoint.com\)](#) or [HIPAA Documents \(tn.gov\)](#)

- The TFPP safeguards to ensure client confidentiality. Information obtained by the TFPP staff about an individual receiving services shall not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual.
- All TFPP staff are required to complete the web-based HIPAA training during new employee orientation and annually. This course is an overview of the Health Insurance Portability and Accountability Act pertaining to Personally Identifiable Information and the privacy guaranteed by this Act to Tennessee citizens.

CHS Policy Confidential Services – 4.8, revised: January 31, 2022. [Family Planning - CHS-4.8 Confidential Services Policy.pdf - Folders \(sharepoint.com\)](#)

## CLIENT DIGNITY & SATISFACTION

The TFPP provides services in a client centered manner , culturally and linguistically appropriate, inclusive, and trauma-informed; protects the individual's dignity; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

- The Tennessee Family Planning program provides services that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.
- Client privacy will be protected during all aspects of their appointment/clinic encounter.
- Client "Bill of Rights" will be posted at the service sites, clearly visible to all clients, that outlines the client's rights and responsibilities. [Family Planning - Client Bill of Rights - Folders \(sharepoint.com\)](#)
- Every service site will conduct a client satisfaction survey once each calendar year for at least five (5) working days using the prescribed satisfaction survey form. [Family Planning - CHS Policy 2.14 P0214\\_PatientSatisfaction.pdf - Folders \(sharepoint.com\)](#)
- Services will be provided in a client centered, respectful, and culturally humble manner.

Every TFPP site conducts a client satisfaction survey to assess client satisfaction with the services they receive and their interactions with staff. [Family Planning - CHS Policy 2.14 P0214 PatientSatisfaction.pdf - Folders \(sharepoint.com\)](#)

- All regional and metro FPA's are responsible for assuring that the Satisfaction Survey, English and Spanish, is made available to clients visiting each clinic site
- Services offered on the days selected for the satisfaction survey should represent the range of services provided by the service site.
- Regional staff, county staff, and central office program staff are responsible for reviewing the information obtained from the survey and implementing appropriate changes to improve client satisfaction.
- Central office TFPP is committed to conducting more frequent and in-depth satisfaction surveys for other purposes (e.g., program evaluation, needs assessment, outcome assessment,).
- Forms used for these purposes are developed in accordance with OPA and TDH departmental standards.

The TFPP provides for community collaboration, participation, and education and promotes activities for the TFPP. The TFPP offers the opportunity for involvement in the development, implementation, and evaluation of the TFPP by persons broadly representative of all significant elements of the population being served and by persons in the community knowledgeable about the community's needs for family planning services.

- To maximize community outreach to better serve those in need of TFPP services, the TFPP provides community education and outreach, reproductive health education, and training to preteens, teens, adults, parents, and professionals in all 95 TN counties. The TFPP fosters community input and engagement to enhance community understanding of family planning and TFPP services.
- The community education program(s) are based on an assessment of the community's needs and contain an implementation and evaluation strategy. Community Education and Outreach (CEO) worksheets are used to identify priority populations to be addressed in the CEO plan. The Community Input Committee (CIC) reviews the family planning outreach plans to ensure the population's needs are met.
- The TFPP staff collaborates and partners internally and externally to promote reproductive health and support TFPP efforts across the state. Collaborations include, but are not limited to: Tennessee Initiative for Perinatal Quality Care (TIPQC), the HIV/STD Program, the Tennessee Breast & Cervical Cancer Screening Program (TBCSP), the Office of Policy, Planning and Assessment (PPA), the Tennessee Adolescent Pregnancy Prevention Program (TAPPP), the Sexual Risk Avoidance Education (SRAE) program, WIC/Nutrition Program, Infant Mortality Program, State Opioid Response team, and State Tobacco Prevention Program. These and other collaborations support and promote strategies that foster quality family planning as an essential component of health care for all.
- The TFPP FPA's are responsible for the creation, implementation, documentation, and progress reporting of their individual Metro/Regional/Agency family planning outreach plans. These plans are reviewed and approved by the I & E Advisory committee and uploaded annually by April 15<sup>th</sup>, [Family Planning - Family Planning Outreach Plans - Folders \(sharepoint.com\)](#). Semi-annual progress reports are due by April 15<sup>th</sup> and October 15<sup>th</sup>.



## FACILITIES AND ACCESSIBILITY OF SERVICES

TFPP strives for all service sites to be geographically accessible for the population being served. FPP sites will consider clients' access to transportation, clinic locations, hours of operation, and other factors that influence clients' abilities to access services. The TFPP does not discriminate based on disability, and facilities are readily accessible to people with disabilities. All TDH employees must complete the web-based Title VI training initially upon employment and annually.

TDH has written policies consistent with the HHS Office for Civil Rights policy document, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 4, 2003) (HHS Grants Policy Statement 2007, II-23). See: GENERAL ADMINISTRATION 2.0, Title VI Limited English Proficiency (LEP) Patient Services – 2.16

Each region has a written LEP plan to provide a framework for timely and reasonable language assistance and eliminate or reduce LEP as a barrier to accessing programs receiving federal financial assistance. Procedures are implemented in each rural public health region. These procedures are designed to determine the appropriate language assistance services to ensure an LEP individual has meaningful access to services.

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## EMERGENCY MANAGEMENT

The Emergency Preparedness Program is responsible for developing plans for the Tennessee Department of Health to protect the health of residents and visitors from the effects of man-made and naturally occurring events.

The TDH Emergency Preparedness (EP) Program coordinates efforts to prepare for, respond to, and recover from public health and medical emergencies. The program collaborates with local, regional, and state agencies, to protect the public and health providers. The program conducts medical volunteer coordination, and provides community survey results, emergency public health alerting, resource coordination, emergency medical response coordination, and outbreak investigations.

Disaster plans (e.g., fire, bomb, terrorism, earthquake.) have been developed by TDH EP and are available to staff to ensure they can identify emergency evacuation routes.

TDH staff has completed emergency preparedness training and understand their role in an emergency or natural disaster. Detailed information on the TDH Emergency Preparedness plan can be found on *SharePoint* at [CEDEP/EP - Home \(sharepoint.com\)](#)

All TDH regions/metros/agencies have a written plan for managing emergencies, and clinic facilities meet applicable standards established by Federal, State, and local governments (e.g., local fire, building, and licensing codes).

Health and safety issues within the TFPP fall under the authority of the Tennessee Occupational Safety and Health Administration (TOSHA). TDH has established an exposure control plan in each region that outlines procedures for eliminating or minimizing employee exposure to blood or other potentially infectious material in the workplace. This plan is based on the 2013 OSHA Bloodborne Pathogen Standards and the Division of Community Health Services Bloodborne Pathogen Infection Control Manual. See *CHS Policy and Procedure Manual SECTION 3 GENERAL MEDICAL* at *SharePoint* Link: [General Medical.pdf \(sharepoint.com\)](#)

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#### STANDARDS OF CONDUCT

The TFPP is required by Title X to establish policies to prevent employees, consultants, or members of governing/advisory bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others (HHS Grants Policy Statement 2007, II-7).

TDH has a Code of Conduct policy (PR-0483 (Rev. 10-14)). See *SharePoint* at: <https://www.tn.gov/content/dam/tn/health/program-areas/intern-docs/Code-of-Conduct.pdf>. All TFPP and TDH employees are expected to act in a manner that will enhance the name, service, and general impression of the State in the eyes of the general public. The TDH Code of Conduct provides general rules of conduct based on fundamental ethical principles. Employees shall also uphold the ethical rules governing their professions and comply with departmental and State ethics policies. No Code of Conduct can provide the absolute last word to address every circumstance. Therefore, employees are expected to use sound judgment in all of their conduct and ask for help when needed.

Failure to comply with the TDH Code of Conduct and any other policies specific to the employee's organizational unit may subject the employee to disciplinary action

according to the Department of Human Resources Rules and Regulations. All employees must read and sign the TDH Code of Conduct before assuming their job responsibilities.

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#### HUMAN SUBJECTS CLEARANCE (RESEARCH)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46).

The TDH ensures compliance with the U.S. Department of Health and Human Services regulations for the protection of human research subjects. All information and documents are available at [www.IRBnet.org](http://www.IRBnet.org). The TDH IRB is convened monthly. TFPP advises OPA in writing of any research projects that involve Title X clients.

#### 340B PHARMACY PROGRAM

The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Manufacturers participating in Medicaid agree to provide outpatient drugs to covered entities at significantly reduced prices.

As covered entities in the 340B Program, the State of Tennessee and the TFPP ensures compliance with all 340B Program requirements and meet the following ongoing requirements:

- Keep 340B OPAIS information accurate and up to date. Register new outpatient facilities and contract pharmacies as they are added.
- Recertify eligibility every year.
- Prevent diversion to ineligible patients. TDH does not resell or otherwise transfer 340B drugs to ineligible clients.
- TFPP and State Pharmacist accurately report how we bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).
- TFPP and State Pharmacist maintain auditable records documenting compliance with 340B Program requirements.

# FORMS AND INSTRUCTIONS

## Family Planning Reports and Due Dates

These reports or documents are to be submitted by the assigned Family Planning Administrator

### **Monthly Reports** - Submit to Family Planning Financial Administrator

- **Family Planning Invoices** - (Contracts, Sterilization and Other Medical Services)
- (Invoices are due as soon as received. Don't wait for the end of the month)
- **Revenue Report**
- **AEL Invoice**

### **Quarterly Reports** (Due April 15<sup>th</sup>, July 15<sup>th</sup>, October 15<sup>th</sup>, January 15<sup>th</sup>)

- **Service Site Information** (Exhibit B)
- [Service Site Information \(Exhibit B\).xlsx \(sharepoint.com\)](#)
- **Services Provided** (Exhibit C)
- [Services Provided \(Exhibit C\).docx \(sharepoint.com\)](#)
- **Quarterly Program Data Review**  
*This quarterly report, based on FP supplemental screen data, will be shared with FPAs after review by FP Director. FPAs are responsible for reviewing this report and utilizing it for programmatic monitoring. FPA's shall review this report and report any errors or concerns within 2 weeks.*

### **Semi-Annual Reports:** April 1<sup>st</sup> thru September 30<sup>th</sup> - **due October 20<sup>th</sup>**

October 1<sup>st</sup> thru March 31<sup>st</sup> – **due April 20<sup>th</sup>**

All forms and reports can be found on **Sharepoint:** [Family Planning - Reports & Forms - Folders \(sharepoint.com\)](#)

- **Family Planning Chart Review Verification** – Upload to Sharepoint: [Family Planning - Chart Review Verification DropBox - Folders \(sharepoint.com\)](#)
- **Training Verification Reports** (Mandatory Child Abuse Reporting & Human Trafficking, Cultural Competency, IPV, Title X, Coercion, other training) Upload to Sharepoint [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#)
- **Family Planning Outreach Plan Progress Report** – Update of FPOP goals and activities upload to Sharepoint: [Family Planning - Community Education and Outreach Plans - Folders \(sharepoint.com\)](#)
- **Administrative Site Visit Reports** Upload to Sharepoint: [Family Planning - Administrative Site Visit Reports DropBox - Folders \(sharepoint.com\)](#)
- **Sterilization Report** (Submit to Family Planning Financial Administrator - This form CANNOT be uploaded into Sharepoint)
- **Family Planning Semi-Annual Progress and Program Accomplishments Report:** Upload to Sharepoint: [Family Planning - Semi-Annual Progress Reports - Folders \(sharepoint.com\)](#). *This is your response to the work plan objectives*

*and what your region/metro has accomplished during this grant cycle. Note any accomplishments/progress (it doesn't have to be on the work plan) or any obstacles you have faced*

## **Annual Reports**

- **Personnel Detail Information - Need by December 1<sup>st</sup>**

### **Due, at least annually, April 1**

- **Family Planning Outreach Work Plan** Upload to appropriate Sharepoint year folder: [Family Planning - Annual FPOP Plans 2022 - Folders \(sharepoint.com\)](#)
- **I & E/Advisory Committee Meetings Documentation and approvals** – Upload to Sharepoint: [Family Planning - I&E Committee Reports DropBox - Folders \(sharepoint.com\)](#)
  - **Forms:** [Family Planning - I & E Committee Forms - Folders \(sharepoint.com\)](#)
    - I & E meeting documentation must include:
    - Meeting Agenda
    - Meeting Minutes
    - Work Plan Review/Approval *This is a required annual review of the FP Work Plan by your committee.*
    - List of Committee members & demographics - [Demographic Information Sheet.docx \(sharepoint.com\)](#)
    - Material Review Forms - forms used to assess & review, and approval/disapproval
    - Sample of each reviewed handouts/brochures/websites/posters
    - I & E Materials Inventory Log - [I E materials inventory log 2020.xlsx \(sharepoint.com\)](#)
    - Any education/updates presented to the committee

### **As Needed**

- **Purchase Requests for Vitamins with Folic Acid:** Metros
- **Regions** - Regional Pharmacist (forward copy of invoice to Financial Administrator when received)

### **Contact Information**

Central Office Family Planning Team members may be contacted individually based upon needs. General family planning email for submission, when things cannot be uploaded to Sharepoint is also available at the Group site:

[FamilyPlanning.Health@tn.gov](mailto:FamilyPlanning.Health@tn.gov)

## **LINKS TO FORMS**

[Family Planning Site Visit Form](#)



[Family Planning Chart Review tool](#)

[Client Bill of Rights](#)

[Exhibit B: FP Service Site Information](#)

[Exhibit C: Services Provided](#)

[Annual FP Outreach Plan Template](#)

[FP Outreach Plan Semi-Annual Progress Report](#)

[Sterilization Report](#)

[Sterilization Consent](#)

[Spanish Sterilization Consent](#)

[Verification of Chart Review](#)

[Verification of FP Required Training](#)

[Training Plan](#)

[Tennessee Department of Health Child Abuse and/or Neglect Report](#)

[Authorization For Services](#)

[Invoice Forms](#)

[Information & Education, Advisory Committee Forms](#)

[Sliding Fee Scale](#)

[Reimbursement Rates](#)

[Family Planning Administrators Contact List](#)

[Telehealth](#)



Tennessee  
Family Planning Program  
Administrative  
Policy & Procedure  
Manual

*Revised May 2022*

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# ACKNOWLEDGEMENTS

**This manual has been revised and updated with the assistance of the following:**

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# ADMINISTRATIVE POLICIES AND PROCEDURES DISCLAIMER

These Administrative Policies were all reviewed and updated by the Tennessee Family Planning central office key staff. Many of these policies, however, were previously implemented and have been reviewed and updated periodically by the TFPP. The documents are available for review at our *Sharepoint* site: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#)

Every reasonable effort will be made to keep this manual current. If errors in content are found you are encouraged to contact the staff at TFPP so that concerns may be addressed, and changes made to the manual as needed. TFPP staff will make updates to this document annually. It is the responsibility of the Family Planning Administrator (FPA) to ensure appropriate staff have read and reviewed the updated manual annually.



# MANAGEMENT & ADMINISTRATION



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### VOLUNTARY PARTICIPATION

Family planning services are to be provided solely on a voluntary basis (Sections 1001 and 1007, PHS Act; 42 CFR 59.5 (a)(2)). Clients cannot be coerced to accept services or to use or not use any particular method of family planning (42 CFR 59.5(a)(2)).

A client's acceptance of family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program that is offered by the grantee or subrecipient (Section 1007, PHS Act; 42 CFR 59.5(a)(2)).

Personnel working within the family planning project must be informed that they may be subject to prosecution if they coerce or try to coerce any person to accept services or to employ or not to employ any particular methods of family planning (Section 205, Public Law 94-63, as set out in 42 CFR 59.5(a)(2) footnote 1).

Policy Information:	Description:
Policy Title	Voluntary Participation
Effective Date	April 1, 2022
Revision Dates	March 4, 2022
Review Due Date	March 2023
References	Providing Quality Family Planning Services: Recommendations from the Centers for Disease Control and Prevention and the U.S. Office of Population Affairs (QFP) Appendix C (pages 45–46) <a href="#">rr6304.pdf (cdc.gov)</a> Code of Federal Regulations 42 CFR 59.5(a)(2) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	March 10, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program process for ensuring compliance with the requirement that family planning services are to be provided solely on a voluntary basis, that a client's acceptance of services must not be a prerequisite to eligibility for any other services, and that personnel will be subject to prosecution if they coerce or try to coerce any person to undergo an abortion or sterilization procedure. All family planning and reproductive health materials, print

and electronic, that The Tennessee Family Planning Program and service sites make available to clients and potential clients must go through the I&E materials review process.

**Policy:**

- Acceptance of family planning program services shall be solely on a voluntary basis and will not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the client
- Services will be provided on a voluntary basis and clients may not be coerced to use any particular method of contraception or services.
- Staff will be informed at least once during the project period that:
  - clients may not be coerced to use contraception, or to use any particular method of contraception or service,
  - family planning services must not be a prerequisite to eligibility for, or receipt of, any other services, assistance from, or participation in any other program,
  - Staff may be subject to prosecution if they coerce, or try to coerce, any person to undergo an abortion or sterilization procedure.
- General consent forms or other documentation at service sites (and/or maintained in electronic health record) will inform clients that services are to be provided on a voluntary basis.
- Each client will sign a general consent form. [Family Planning - PH-1530 GENERAL CONSENT\\_English Rev. 03-2020.pdf - Folders \(sharepoint.com\)](#)
- Administrative policies at service sites include a written statement that receipt of family planning services will not be a prerequisite to receipt of any other services offered by the service site.
- General consent forms or other documentation provided to clients will state that receipt of family planning services is not a prerequisite to receipt of any other services offered by the service site.
- If any family planning services are not provided directly, subcontracts for family planning services will specify that administrative policies used by service sites include a written statement that services are provided on a voluntary basis.

**Procedure:**

- All staff involved in Family Planning are required to complete annual training on specific Family Planning policies and procedures including Voluntary Participation. Staff are trained upon initial employment orientation and annually thereafter.
- Specific training verification forms are used, by the Family Planning Administrator, to report completed trainings to Central Office program staff. Semi-annual Reports are uploaded into SharePoint [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Tennessee family planning central office staff monitors FPA's and service sites to ensure compliance with this requirement.
  - Central Office Family Planning Program staff monitors training records uploaded into SharePoint to ensure compliance with this requirement.
  - Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant period.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### PROHIBITION OF ABORTION & REFERRAL FOR ABORTION

Title X grantees and sub-recipients must be in full compliance with Section 1008 of the Title X statute, which prohibits abortion as a method of family planning, 42 CFR 59.5(a)(5), which prohibits projects from providing, promoting, referring for, or supporting abortion as a method of family planning, and 42 CFR 59.14(a), which bars referral for abortion as a method of family planning. Grantee has documented processes to ensure that they and their sub-recipients are in compliance with Section 1008 and 42 CFR 59.5(a)(5) and 59.14(a). Grantees include language in sub-recipient contracts addressing these requirements.

Policy Information:	Description:
<b>Policy Title</b>	Prohibition of Abortion & Referral for Abortion
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Section 1008 of the Title X Statute  <a href="https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf">https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf</a></p> <p>Code of Federal Regulations 42 CFR Part 59.14(a) and 59.5(a)(5)  <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 11, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with requirements that prohibit providing, promoting, referring for, or supporting abortion as a method of family planning; and referring for abortion as a method of family planning.

#### Policy:

- TFPP ensures that abortion is NOT provided as a method of family planning.
- Family Planning staff must:
  - Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:
    - Prenatal care and delivery
    - Infant care, foster care, or adoption
    - Pregnancy termination
- If requested to provide such information and counseling, TFPP staff will provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

- TFPP contracts with subrecipients include language addressing the requirement prohibiting:
  - Sites from providing abortion as a method of family planning.
  - TFPP service sites have written policies or procedures that prohibit:
    - Providing abortion as a method family planning.
    - Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:
      - Prenatal care and delivery
      - Infant care, foster care, or adoption
      - Pregnancy termination
      - If requested to provide such information and counseling, staff will provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.
- Financial documentation at all TFPP service sites will demonstrate that Title X funds are not being used for abortion services.

**Procedure:**

- All staff involved in the TFPP are required to complete annual training on specific Family Planning policies and procedures including Prohibition of Abortion & Referral for Abortion.
- Specific training verification forms are used, by the Family Planning Administrator, to report completed trainings to Central Office program staff. Semi-annual Reports are uploaded into *SharePoint* [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Tennessee family planning central office staff monitors FPA's and service sites to ensure compliance with this requirement.
  - Central Office Family Planning Program staff monitors training records uploaded into SharePoint to ensure compliance with this requirement.
  - Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant period.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### AUTHORIZED PURCHASES

All services purchased for project participants will be authorized by the project director or their designee on the project staff [42CFR 59.5 (b)(7)]

Policy Information:	Description:
<b>Policy Title</b>	Authorized Purchases
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Program Requirements for Title X Funded Family Planning Projects, Version 1.0 April 2014 <a href="https://opa.hhs.gov/sites/default/files/2021-03/title-x-program-requirements-april-2014.pdf">https://opa.hhs.gov/sites/default/files/2021-03/title-x-program-requirements-april-2014.pdf</a> [42CFR 59.5 (b)(7)]  Comprehensive rules and regulations of the central procurement office. <a href="https://publications.tnsosfiles.com/rules/0690/0690-03-01.20140120.pdf">https://publications.tnsosfiles.com/rules/0690/0690-03-01.20140120.pdf</a>  Procurement: <a href="https://www.tn.gov/generalservices/procurement/central-procurement-office--cpo-/library-.html">https://www.tn.gov/generalservices/procurement/central-procurement-office--cpo-/library-.html</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** To describe TFPP fiscal policy regarding authorization of purchasing by the TFPP project director. This policy applies to all TFPP purchases.

#### Policy:

This policy addresses the fiscal policy regarding authorized purchasing by the TFPP project director or their designee.

#### Procedure:

- For the TFPP, all purchases are made with the prior approval of the Director, or in the Director's absence, by the designated alternate. Any single equipment item with a purchase price of \$5000.00 shall be considered capital; less than \$5000.00 shall be considered small equipment or supplies.
- Purchasing decisions will be based on quality, cost, and competition for the required product. When able to do so, the Director will bulk purchase and/or obtain competitive bids (particularly for major items of \$2000 or more) to assure cost savings to the program.
- Any bids or offers may be rejected by the grantee or subrecipients when it is in the best interest to do so.
- The process for reviewing purchasing decisions will be reviewed during grantee's site review with the subrecipient and in monthly or quarterly fiscal report reviews submitted to the grantee

- TFPP central office staff are trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed.
- TFPP staff may access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### SUBRECIPIENT INCLUSION IN GRANTEE POLICY ESTABLISHMENT

Subrecipient agencies must be given an opportunity to participate in the establishment of ongoing grantee policies and guidelines (42 CFR 59.5(a)(10)).

Policy Information:	Description:
<b>Policy Title</b>	Subrecipient Inclusion in Policy Establishment
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 22, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(a)(10) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 23, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program (TFPP) process for ensuring TFPP agencies are given an opportunity to participate in the establishment of ongoing grantee policies and guidelines.

**Policy:** To improve the development of guidelines through meaningful and equitable multi-stakeholder engagement, and subsequently to improve health outcomes and reduce inequities in health, TFPP and TDH will provide opportunity(s) for contracted agencies and TDH staff to participate in the establishment of ongoing grantee policies and guidelines.

#### Procedure:

- TDH and TFPP collaborates with statewide TFPP administrators and multiple and diverse stakeholders to encourage engagement in guideline development and implementation.
- Proposed policies, processes, standards, and procedures are developed in collaboration with CHS
- Public Health Nursing Practice committee reviews and updates public health nursing protocols by investigating recommendations regarding standards, guidelines, and policies. The practice committee consists of one public health nurse from each rural region and one representative from two of the metropolitan areas.
- The Medical Leadership Team provides medical guidance, reviews, and updates to public health protocols by investigating recommendations regarding standards, guidelines, and policies.
- Proposed policies (or modifications to existing policies) are presented to the Policy Review Committee for review and recommendation. The committee reviews those recommendations and may approve as written, make modifications, and approve as modified, or reject the recommendation.

- Additional activities that TFPP conduct to involve subrecipients in the establishment of grantee policies and guidelines include:
  - Monthly FPA meetings
  - Biannual MCH Stakeholders Meetings
  - Continuing education of health care partners and staff in clinical guidelines
  - Community health communication campaigns and education
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### FINANCIAL MANAGEMENT SYSTEM

The grantee and each subrecipient must maintain a financial management system that meets Federal standards, as applicable, as well as any other requirements imposed by the Notice of Award, and which complies with Federal standards that will support effective control and accountability of funds, as required (45 CFR 75.302).

Policy Information:	Description:
<b>Policy Title</b>	Financial Management System
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 21, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	45 CFR 75.302 - Financial management and standards for financial management systems <a href="https://www.govinfo.gov/app/details/CFR-2016-title45-vol1/CFR-2016-title45-vol1-sec75-302">https://www.govinfo.gov/app/details/CFR-2016-title45-vol1/CFR-2016-title45-vol1-sec75-302</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 22, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program (TFPP) process for ensuring compliance with the requirement to maintain financial management systems that meet Federal standards. TFPP will comply with all requirements imposed by the Notice of Award, and which comply with Federal standards that will support effective control and accountability of funds. as applicable.

#### Policy:

- TFPP will maintain financial management systems that meet Federal standards, as well as any other requirements imposed by the Notice of Award, and which comply with Federal standards that will support effective control and accountability of funds.

#### Procedure:

- TFPP and the Department of Health (TDH) shall maintain financial policies and procedures in line with Federal standards.
- TFPP has a process for tracking revenues and expenditures associated with the Title X project.
- All Programs within the Department of Health that have contracts , including TFPP, are impacted by Standard Operating Procedure (SOP). All contractual invoices that are received will be processed as outlined in the SOP. [Contractual Payments.docx \(sharepoint.com\)](#)
- TFPP make required forms available electronically via *Edison* and/or *Sharepoint* to all project providers.
- TFPP project staff submit reports to the central office financial officer according to the deliverable timeline and contract.
- TFPP service providers submit FTE data as part of the FPAR according to the deliverable timeline and contract. FTE data must capture and reflect only the activity time of each employee directly associated with supporting and providing Title X services.

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- TFPP Director, or designee, will review the report and FTE data to ensure appropriate use and expenditure of Title X funds.
- Fiscal reviews will be performed by Internal Audit staff and be completed at TFPP site visit reviews.
- The state accounting team follows all General Accepted Accounting Principles (GAAP) in the review/monitoring process to provide reasonable assurance regarding the achievement of objectives in the following categories:
  - Effectiveness and efficiency of operations
  - Reliability of financial reporting; and
  - Compliance with applicable law and regulations.
- State Internal controls pertaining to the compliance requirements for federal programs are designed to provide reasonable assurance regarding the achievement of the following objectives:
  - Transactions are properly recorded and accounted for to:
  - Permit the preparation of reliable financial statements and federal reports;
  - Maintain accountability over assets; and
  - Demonstrate compliance with laws, regulations, and other compliance requirements;
- Transactions are executed in compliance with:
  - Laws, regulations, and the provisions of contracts or grant agreements that could have a direct and material effect on a Federal program; and
  - Any other laws and regulations that are identified in the compliance supplements; and
- Funds, property, and other assets are safeguarded against loss from unauthorized use or disposition.
- Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- Detailed Finance & Administration (F&A) Policies may be accessed at:  
<https://www.tn.gov/finance/looking-for/policies.html>



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### FEDERAL POVERTY LEVEL GUIDANCE, THIRD PARTY BILLING, AND INCOME VERIFICATION

Clients whose documented income is at or below 100% of the Federal Poverty Level (FPL) must not be charged, although projects must bill all third parties authorized or legally obligated to pay for services (Section 1006(c)(2), PHS Act; 42 CFR 59.5(a)(7)).

For the purposes of considering payment for contraceptive services only, where an individual has health insurance coverage through an employer that does not provide the contraceptive services sought by the individual because the employer has a sincerely held religious or moral objection to providing such coverage, the project director may consider their insurance coverage status as a good reason why she is unable to pay for contraceptive services, as detailed in (42 CFR 59.2). In this case the client is then coded as Payor 6 and charged based on sliding fee scale.

Although not required to do so, grantees who have lawful access to other valid means of income verification because of the client's participation in another program may use those data, rather than re-verify income or rely solely on the client's self-report.

Policy Information:	Description:
Policy Title	Federal Poverty Level Guidance, Third Party Billing, and Income Verification
Effective Date	April 1, 2022
Revision Dates	March 4, 2022
Review Due Date	May 2023
References	Code of Federal Regulations 42 CFR 59.2 and 59.5(a)(7) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	May 2022

**Purpose:** To ensure consistent implementation of Title X policy for charges to clients for family planning services. The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring grantee and subrecipient compliance with the requirement that clients whose documented income is at or below 100% of the FPL will not be charged fees for Title X services provided to them, and that third parties authorized or legally obligated to pay for services will be billed.

**Policy:**

- Clients will not be denied project services or subjected to any variation in quality of services because of inability to pay.

- Tennessee has established a sliding scale schedule of discount rates at Tennessee Department of Health local and regional health clinics.
- A schedule of discounts, based on ability to pay, is required for individuals receiving family planning services with family incomes between 101% and 250% of the FPL.
- The sliding scale schedule of discounts will be set at a uniform rate in PTBMIS for all self-pay clients receiving family planning services.
- There will not be a general policy of no fee or flat fees for the provision of services to minors, or a schedule of fees for minors that is different from other populations receiving family planning services.
- Clients whose documented income is at or below 100% of the FPL will not be charged for family planning services.
- Third party payers will be billed when authorized or legally obligated to pay for services.
- Income verification lawfully obtained for the client's participation in another program may be used, rather than re-verify income or rely solely on the client's self-report.
- Client income verification will be aligned with Title X program requirements and will not present a barrier to receipt of services.

**Procedure:**

- The standard sliding scale discount will be set at 250% of federal poverty level (FPL) for all Family Planning Program clients.
- The client receiving Family Planning Services whose income is at or below 100% of the Federal Poverty Level will not be charged any amount for the service(s).
- A client receiving Family Planning Services whose income is between 101% and 250% of the Federal Poverty Level will be charged an amount(s) based on a Schedule of Discounts (sliding fee scale).
- To be eligible for the Schedule of Discounts, a client must declare income at registration at the initial visit and every 12 months thereafter. If the client refuses to provide this information, the field on the financial information screen titled "Sliding Scale" should be set to 'N'.
- A client receiving Family Planning Services who is covered by an insurance plan that assigns a copay, coinsurance, or deductible will be charged the lesser of a charge determined by the Schedule of Discounts or the assigned copay, coinsurance, or deductible.
- A client requesting Family Planning services who is unable to obtain employer-sponsored insurance coverage for certain contraceptive services, due to their employer's religious beliefs or moral conviction, is considered underinsured and therefore eligible for Title X / Family Planning services at the sliding fee scale rates.
- Charges to minor clients receiving confidential family planning services will be based on the income of the minor.
- The Commissioner of Health has the authority to waive fees for services. For fees to be waived, a written request, which must include the type of service being received and an explanation of why the waiving of fees is being requested, shall be submitted to the Assistant Commissioner of CHS via the appropriate Regional Director. The request will then be sent to the Office of the Commissioner of Health for final approval.
- No client will be refused Family Planning Services based on inability to pay or refusal to declare income.
- For family planning service clients covered by insurance, client charges for copay, coinsurance, or deductible will be transferred to the client based on the Schedule of Discounts using family size and household income, after the remittance is received from the insurance plan.
- The Family Planning schedule of discounts, used by the Family Planning Program project sites, shall be updated, and disbursed annually to match the corresponding FPL guidelines.
- The Family Planning Program will ensure that staff are using the most recent FPL guidelines and schedule of discounts by monitoring during Central Office and Family Planning Administrators site visits.
- Staff will be trained on Family Planning policies and procedures including Federal Poverty Level Guidance, Third Party Billing, and Income Verification upon initial onboarding. Updates or



changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.

- Tennessee family planning central office staff monitors service sites to ensure compliance with this requirement.
- Staff can access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#) A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### DISCOUNT SCHEDULES

A schedule of discounts, based on ability to pay, is required for individuals with family incomes up to 250% of the Federal Poverty Level (FPL) (42 CFR 59.5(a)(8)).

Policy Information:	Description:
<b>Policy Title</b>	Discount Schedules
<b>Effective Date</b>	May 20, 2019
<b>Revision Dates</b>	March 7, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Office of Population Affairs, Program Requirements for Title X Funded Family Planning Projects, Version 1.0, April 2014 Code of Federal Regulations 42 CFR 59.5(a)(8) <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A</a> Sliding Scale Schedule of Discounts- 4.17 - <a href="#">Family Planning - CHS-4.17 Sliding Scale Schedule of Discounts Policy.pdf - Folders (sharepoint.com)</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	May 2022

**Purpose:** The purpose of this policy is to describe TFPP process for ensuring compliance with the requirement that projects must provide a schedule of discounts, based on ability to pay, for individuals with family incomes up to 250% of the Federal Poverty Level

### Policy:

This policy addresses the *Discount Schedule and Sliding Fee Scale* that the TFPP utilizes for all clients receiving TFPP services. This schedule of discounts is set at a uniform rate in PTBMIS and updated annually. [Sliding Scale 2 11 22.xlsx \(sharepoint.com\)](#)

### Procedure:

- The standard sliding scale discount will be set at 200% of federal poverty level (FPL) for all TDH services in PTBMIS with the exception of services performed under the Family Planning Program.
- The sliding scale schedule of discounts for Family Planning services will be assessed at 250% of FPL.
- Patient financial information must be up to date to ensure accuracy and consistency when applying the sliding fee scale to patient charges.
- All patients are asked to provide their household income and family size at every visit.
- TFPP central office staff are trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed.

- TFPP staff may access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### FEE WAIVER

Fees may be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good reasons, to pay for family planning services (42 CFR 59.2).

Policy Information:	Description:
<b>Policy Title</b>	Fee Waiver
<b>Effective Date</b>	July 1, 2019,
<b>Revision Dates</b>	March 7, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.2 <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a> Waiving Fees – 4.21 - <a href="#">Family Planning - CHS Waiving Fees – 4.21 3.22.pdf - Folders (sharepoint.com)</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 21, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program (TFPP) process for ensuring compliance with the requirement that no client will be denied services due to inability to pay, by waiving fees or payments for individuals with family incomes above 100% of the FPL, who are unable, for good reasons, to pay for family planning services provided through the Title X-funded project.

#### Policy:

- Fees and payments will be waived for individuals with family incomes above 100% of the FPL, who are unable, for good reasons, to pay for family planning services provided through the Title X-funded project.
- The site director (or designee) is responsible for making determinations regarding waiver of charges.

#### Procedure:

- The Commissioner of Health has the authority to waive fees for services.
- For fees to be waived, a written request, which must include the type of service being received and an explanation of why the waiving of fees is being requested, shall be submitted to the Assistant Commissioner of CHS via the appropriate Regional Director. The request will then be sent to the Office of the Commissioner of Health for final approval.
- No patient will be refused Family Planning services based on inability to pay or refusal to declare income.

- Each TFPP site has policies and procedures to refer clients (or financial records) to the service site director (or designee) for review and consideration of waiver of charges.
  - when the client does not have documented income at or below 100% of the FPL but who are unable, for good cause, to pay for family planning services.
- Policies and Procedures at the TFPP service site demonstrates when a determination is made by the service site director and documents the process of informing the clients about determination of the waiver.
  - Documentation records will be maintained at each TFPP service site to document:
    - The site directors' determination, and
    - That the client was informed of the site director's determination.
- The Regional/Metro FPA ensures that all sites have an individual, site specific, *Fee Waiver policy and procedure* by monitoring during annual administrative site visits.
- The TFPP central office staff monitors FP service sites to ensure compliance with this *Fee Waiver policy and procedure* requirement. These site visits are conducted at least once per grant cycle.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- Staff may access the state of Tennessee's "*Charges for Patients Receiving Family Planning Services – 4.12*" waiver policy virtually on Sharepoint: [Family Planning - Good Cause Waiver 4.12 Charges for Patients Receiving Family Planning Services \(1\).pdf - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### REASONABLE COSTS/FEE SCHEDULES

For persons from families whose income exceeds 250% of the Federal Poverty Level (FPL), charges must be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services (42 CFR 59.5(a)(8)).

Policy Information:	Description:
<b>Policy Title</b>	Reasonable Costs/Fee Schedules
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 21, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(a)(8) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59.15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59.15</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 21, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program (TFPP) process for ensuring compliance with the requirement that, for persons from families whose income exceeds 250% of the FPL, charges will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services

#### Policy:

- A schedule of discounts, based on ability to pay, is required for individuals receiving family planning services with family incomes between 101% and 250% of the FPL.
- Charges for providing family planning services through the Title X Project, to persons from families whose income exceeds 250% of the FPL, will be based on a schedule of fees designed to recover the reasonable cost of providing services.

#### Procedure:

- The TDH prepares a schedule of fees for the provision of its services consistent with locally prevailing rates or charges and designed to cover reasonable costs of operation as determined by CMS. TDH follows Medicare coding and reimbursement guidelines and adjusts for geographical differences in resource costs. These Fee Schedules are updated annually.
- A client receiving TFPP services whose income is at or below 100% of the Federal Poverty Level will not be charged any amount for the service(s).
- A client receiving TFPP services whose income is between 101% and 250% of the Federal Poverty Level will be charged an amount(s) based on a Schedule of Discounts (sliding fee scale).



- To be eligible for the Schedule of Discounts, a client must declare income at registration at the initial visit and every 12 months thereafter. If the client refuses to provide this information, the field on the financial information screen titled "Sliding Scale" should be set to 'N'.
- A client receiving TFPP services who is covered by an insurance plan that assigns a copay, coinsurance, or deductible will be charged the lesser of a charge determined by the Schedule of Discounts or the assigned copay, coinsurance, or deductible. A client requesting TFPP services who is unable to obtain employer-sponsored insurance coverage for certain contraceptive services, due to their employer's religious beliefs or moral conviction, is considered underinsured and therefore eligible for TFPP services at the sliding fee scale rates.
- Charges to minor clients receiving confidential TFPP services will be based on the income of the minor.
- The Commissioner of Health has the authority to waive fees for services. For fees to be waived, a written request, which must include the type of service being received and an explanation of why the waiving of fees is being requested, shall be submitted to the Assistant Commissioner of CHS via the appropriate Regional Director. The request will then be sent to the Office of the Commissioner of Health for final approval.
- No client will be refused TFPP services based on inability to pay or refusal to declare income.
- For family planning service clients covered by insurance, client charges for copay, coinsurance, or deductible will be transferred to the client based on the Schedule of Discounts using family size and household income, after the remittance is received from the insurance plan
- TFPP central office staff and Regional/Metro FPA's monitor service sites to ensure compliance with this requirement.
  - The Regional/Metro FPA ensure that staff are using the most recent FPL guidelines and schedule of discounts by monitoring during annual administrative site visits.
  - Central Office Key staff ensure compliance during site monitoring visits at least once per grant cycle.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### VOLUNTARY DONATIONS

Voluntary donations from clients are permissible; however, clients must not be pressured to make donations, and donations must not be a prerequisite to the provision of services or supplies.

Policy Information:	Description:
<b>Policy Title</b>	Voluntary Donations
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 22, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Section 1008 of the Title X Statute  <a href="https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf">https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a_0.pdf</a></p> <p>Code of Federal Regulations 42 CFR Part 59.14(a) and 59.5(a)(5)  <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a></p>
<b>Approved by Signature</b>	<p>Danni Lambert, RN</p> <p>State Family Planning Director</p>
<b>Approved Date</b>	March 23, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program (TFPP) process for ensuring compliance with the collection of voluntary donations from clients. This policy establishes a formal process for acceptance and documentation of donations made to the Family Planning Program. This policy provides guidance when individuals, community groups, and businesses wish to make donations to the Family Planning Program. This policy also establishes the standards regarding the acceptance of gifts during the provision of Family Planning services.

#### Policy:

- Voluntary donations from clients are permissible; however, clients are never pressured to make donations, and donations are not a prerequisite to the provision of services or supplies. Donations from clients do not waive the billing/charging requirements.
- Donations may be offered in the form of cash, real or personal property and can be designated or undesignated
  - Designated donations – donations are required to be used for TFPP services
  - Undesignated donations – donations given to the State for an unspecified use
- Designated donations may only be accepted when they have a purpose consistent with the TFPP goals and objectives and are in the best interest of the state of Tennessee. The state must always consider the public trust and comply with all applicable laws when accepting donations.
- A donation of goods or property to any TDH regional office, program area or health department clinic within the Division of Community Health Services (CHS) is considered to be a donation to

the State of Tennessee. Provisions set out in T.C.A. 12-1-101 et seq. [Tenn. Code Ann. § 12-1-101](#) must be followed in order to accept any donations.

**Procedure:**

- Prior to accepting a donation of goods or property, the section program area or clinic site must request approval. If approved CHS administration will notify the Division of Administrative Services (DAS) Property and Procurement Section (PAP). PAP will send the site receiving the donation an Acknowledgment of Donation letter which must be completed and notarized.
- If the property, by definition, requires a state property tag, the notarized letter along with the name and address of the donor, cost, serial number, complete description, and location of the property must be returned to PAP. The donated property will then be placed on the inventory list.
- If the property, by definition, does not require a state property tag, the notarized letter along with the name and address of the individual making the donation must be returned to PAP.
- PAP will be responsible for ensuring that an acknowledgment letter is sent to the person(s) making the donation.
- Based on the value of the donation offer, appropriate State/County/Program staff will review the conditions of any designated donation and determine if the benefits to be derived warrant acceptance of the donation.
- Acknowledgement of the donation should be in writing and be the responsibility of the clinic site Director that received the donation. Undesignated donations shall be acknowledged by the appropriate State/County/Program staff
- Documentation (e.g., signage, scripts) that demonstrates clients are not pressured to make donations and that donations are not a prerequisite to the provision of services or supplies.
- TFPP central office staff monitors FPA's and service sites to ensure compliance with this requirement.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### DISCOUNT ELIGIBILITY FOR MINORS

Eligibility for discounts for unemancipated minors who receive confidential services must be based on the resources of the minor, provided that the Title X provider has documented its efforts to involve the minor's family in the decision to seek family planning services (absent abuse and, if so, with appropriate reporting) (42 CFR 59.2).

Policy Information:	Description:
<b>Policy Title</b>	Discount Eligibility for Minors
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 21, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Eligibility for discounts for unemancipated minors who receive confidential services must be based on the income of the minor (42 CFR 59.2). <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.2">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.2</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 22, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program (TFPP) process for ensuring compliance with the requirement that discounts for unemancipated minors who receive confidential Title X services are based on the resources of the minor (42 CFR 59.2).

#### Policy:

- Eligibility for discounts for unemancipated minors seeking or receiving confidential services in the Title X Project are based solely on the adolescent's resources.
- TDH CHS Policy – *Charges for Patients Receiving Family Planning Services- 4.12* Charges to minor patients receiving confidential family planning services will be based on the income of the minor [Family Planning - CHS-4.12 Charges for Patients Receiving Family Planning Services Policy.pdf - Folders \(sharepoint.com\)](#)

#### Procedure:

- There is a written process for determining whether a minor is seeking confidential services (e.g., question on intake form).
- There is a written process for assessing minor's resources (e.g., income).
- Staff are trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.

- TFPP staff may access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### THIRD PARTY PAYMENTS

Where there is legal obligation or authorization for third party reimbursement, including public or private sources, all reasonable efforts must be made to obtain third party payment without the application of any discounts (42 CFR 59.5(a)(9)).

Family income should be assessed before determining whether copayments or additional fees are charged. With regard to insured clients, clients whose family income is at or below 250% the Federal Poverty Level (FPL) should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

Policy Information:	Description:
<b>Policy Title</b>	Third Party Payments
<b>Effective Date</b>	May 2022
<b>Revision Dates</b>	May 15, 2022
<b>Review Due Date</b>	May 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(a)(9) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59.15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59.15</a>  CHS Policies and Procedures Manual - <a href="#">Section 4 Billing and Operational Support</a> (Sharepoint)
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with the requirement that the Title X Project makes all reasonable efforts to obtain third party payment, without the application of discounts, from all public and private third-party reimbursement sources authorized or legally obligated to pay for services.

#### Policy:

- Clients presenting to a TFPP service site with private insurance will have their charges submitted to their health plan by the health department according to the health plans guidelines.
- If a client presents for TFPP services and is enrolled with a private insurance plan, the health service site should encourage client to seek service from a provider participating with his/her insurance plan except for Family Planning and Communicable Disease services. If services are rendered under Family Planning or Communicable Disease Programs, client charges will be adjusted according to program guidelines



- All reasonable efforts will be made to bill and obtain third party payment, without the application of discounts, from all public and private of third-party reimbursement sources authorized or legally obligated to pay for services.
- Family income will be assessed before determining whether copayments or additional fees are charged.
- Insured clients whose family income is at or below 250% of the FPL will not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

**Procedure:**

- The TennCare eligibility system must be checked for TennCare coverage at each visit. If the client is determined to have TennCare coverage, staff must verify the TennCare policy number by accessing the appropriate website. Any new or incorrect billing information must be updated/corrected in PTBMIS or the successor practice management system. *See the CHS policy on billing TennCare.*
- Client financial information must be up to date to ensure accuracy and consistency when applying the sliding fee scale to client charges. To be eligible for the sliding fee, the client must declare household income and family size at the initial visit, and every 12 months thereafter. TFPP staff must verify that all clients have a current financial information screen listing the family size and household income.
- If the client has only private insurance, the client's eligibility in the health plan should be confirmed by accessing the appropriate website. Proof of insurance must be retained in the client's record.
- All charges should be submitted to insurance for processing and payment. If payment is denied, appropriate follow-up procedures must be performed and documented.
- When the remittance is received from the insurance company, charges for non-covered services by the client's insurance plan will be transferred to the client based on the sliding fee scale according to household income and family size. The exception is adult vaccines.
- The client will be responsible for 100% of the copay, deductible, coinsurance, or cost sharing amount indicated by the remittance advice, with the exception of services that are coded to the Family Planning and Communicable Disease programs. For services provided under the Communicable Disease programs, the copay, deductible, coinsurance, or cost sharing amounts are to be adjusted to zero. For services provided under the Family Planning program, amounts for copay, deductible, coinsurance, or cost sharing will be transferred to the client based on the sliding fee scale using family size and household income.
- If payment is denied due to health department error and cannot be rebilled, the charges will be adjusted to zero and the client will not be responsible for payment.
- At the conclusion of every visit, clients must stop at the checkout counter. Encounters must be keyed and finalized and clients must be made aware of any balance owed. A confidential attempt must be made to collect any balance due at each visit.
- Central Office Family Planning Program staff monitors to ensure compliance with this requirement as part of the Family Planning Program site visit at least once per grant period.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### CONFIDENTIAL COLLECTIONS

Reasonable efforts to collect charges without jeopardizing client confidentiality must be made (42 CFR 59.11).

Policy Information:	Description:
Policy Title	Confidential Collections
Effective Date	February 27, 2019
Revision Dates	January 31, 2022
Review Due Date	January 2023
References	Code of Federal Regulations 42 CFR 59.5(a)(9) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a> CHS Policies and Procedures Manual - <a href="#">Section 4 Billing and Operational Support</a> (Sharepoint) Confidential Services
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring grantee and subrecipient compliance with the requirement that reasonable efforts to collect charges be made without jeopardizing client confidentiality.

#### Policy:

TFPP ensures clients that request confidential services will not receive an explanation of benefits (EOB) from a health plan or a patient statement from the TFPP or TDH.

#### Procedure:

- If a client presents at a TFPP clinic and requests to be registered as a confidential client, the registration screen in PTBMIS will be updated with a "Y" in the confidential contact field so that no client statement will be received from the TFPP visit, unless an alternate address is provided by the client.
- If verified that the client has *TennCare* only, confidential charges can be submitted to the *TennCare* MCO. If client has private insurance and *TennCare* all confidential services must be coded to the client (payer 6) and a credit memo issued for any balance(s) assessed on services that are covered by *TennCare*.
- If client has private insurance only all confidential services must be coded to the client (payer 6). If the client is a minor, then the income must be reported as the client's income only.
- At the conclusion of every visit, clients must stop at the checkout counter. Encounters must be keyed and finalized and clients must be made aware of any balance owed.

- Central Office Family Planning Program staff monitors to ensure compliance with this requirement as part of the Family Planning Program site visit at least once per grant period.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### PERSONNEL POLICIES

Grantees and subrecipients are obligated to establish and maintain personnel policies that comply with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations

Policy Information:	Description:
<b>Policy Title</b>	Personnel Policies
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Title VI of the Civil Rights Act <a href="https://www.justice.gov/crt/title-vi-1964-civil-rights-act">https://www.justice.gov/crt/title-vi-1964-civil-rights-act</a></p> <p>Titles I of the Americans with Disabilities Act of 1990 (ADA) <a href="https://www.eeoc.gov/laws/statutes/ada.cfm">https://www.eeoc.gov/laws/statutes/ada.cfm</a></p> <p>TDH Non-Discrimination policy - <a href="#">Family Planning - Title VI Nondiscrimination 2022.pdf - Folders (sharepoint.com)</a></p> <p>TDH ADA Policy - <a href="#">Family Planning - TDH-ADA-Policy-2022.pdf - Folders (sharepoint.com)</a></p> <p>Department of Human Resources Policies and Resources - <a href="https://www.tn.gov/hr/pr/policies-by-category.html">https://www.tn.gov/hr/pr/policies-by-category.html</a>  <a href="https://publications.tnsosfiles.com/rules/1120/1120-02.20190815.pdf">https://publications.tnsosfiles.com/rules/1120/1120-02.20190815.pdf</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with applicable Federal and State requirements, including Title VI of the Civil Rights Act, Section 504 of the Rehabilitation Act of 1973, Title I of the Americans with Disabilities Act, and the annual appropriations language.

#### Policy:

- TFPP and TDH has established and maintains general personnel policies that address at a minimum:
  - Non-discrimination in personnel administration within any of the organizations funded through the Title X Project
  - Staff recruitment
  - Staff selection
  - Performance evaluation
  - Promotion

- Termination
- Compensation
- Benefits
- Employee grievances

**Procedure:**

- TDH maintains written policies procedures for staff recruitment, staff selection, performance evaluation, promotion, termination, compensation, benefits, staff orientation.
- TDH personnel policies are updated annually.
- TFPP staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff may access the state of Tennessee's DOHR at: <https://www.tn.gov/hr/pr/forms-documents.html> and on Share point at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version of this policy is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### CULTURAL COMPETENCY

Project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population (42 CFR 59.5 (b)(10)).

Policy Information:	Description:
<b>Policy Title</b>	Cultural Competency
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 10, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	National Standards for Culturally and Linguistically Appropriate Services (CLAS) <a href="https://thinkculturalhealth.hhs.gov/clas">https://thinkculturalhealth.hhs.gov/clas</a>  Code of Federal Regulations <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 21, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program

process for ensuring compliance with the requirement that project staff should be broadly representative of all significant elements of the population to be served by the project, and should be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population.

**Policy:**

- Family Planning Project staff will be broadly representative of all significant elements of the population to be served by the Title X Project.
- Family Planning Project staff will receive training in order to be sensitive to, and able to deal effectively with, the cultural and other characteristics of the client population.
- Clients will be assessed for the degree to which they feel staff is sensitive to and able to deal effectively with the client population.
- Documentation at service sites includes records of cultural competence training, in-services, client satisfaction surveys, or other documentation that supports culturally competent services.

**Procedure:**



- All family planning staff are required to complete annual Title VI Training. All state governmental entities that are recipients of Federal financial assistance comply with the requirements of Title VI of the Civil Rights Act of 1964 pursuant to the State of Tennessee Public Acts, 2009 Public Chapter No. 437. Title VI prohibits discrimination on the basis of race, color, or national origin in programs and activities receiving Federal financial assistance.
- To identify populations that may be in need of culturally competent care, Health Councils exist in all 95 counties with TDH directly supporting those councils. Each county brings together diverse stakeholders to look at data, identify disparities, and select priority areas to work on. Building on local expertise and community engagement and with focus on vulnerable populations.
- All service site directors are responsible for assuring that a Satisfaction Survey, for English and Spanish, is made available to patients visiting each site for a period of, at least five (5) working days during the calendar year. Services offered on the days selected for the satisfaction survey shall be representative of the range of clients and services provided by the Family Planning Program.
- All staff involved in Family Planning are required to complete annual training on specific Family Planning policies and procedures including Cultural Competency. Staff are trained upon initial employment orientation and annually thereafter.
- Specific training verification forms are used, by the Family Planning Administrator, to report completed trainings to Central Office program staff. Semi-annual Reports are uploaded into Sharepoint [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Central Office Family Planning Program staff monitors training records uploaded into Sharepoint to ensure compliance with this requirement and that all guidelines are met
- Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant cycle.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### STAFF TRAINING AND PROJECT TECHNICAL ASSISTANCE

Projects must provide for the orientation and in-service training of all project personnel, including the staff of subrecipient agencies and service sites (42 CFR 59.5(b)(4)).

The project's orientation/in-service training includes annual training on Federal/State and local laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, intimate partner violence, as well as on human trafficking (42 CFR 59.17).

The project's orientation/in-service training should include training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities (42 CFR 59.2, 59.17).

Policy Information:	Description:
<b>Policy Title</b>	Staff Training and Project Technical Assistance
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(b)(4), 59.2, and 59.17 <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program(TFPP) process for ensuring compliance with the requirement that the TFPP project provides for the orientation and in-service training of all TFPP personnel. Training of TFPP staff includes annual training on Federal/State and local laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, intimate partner violence, as well as on human trafficking; and annual training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

**Policy:**

- All new TFPP staff will be required to complete an orientation that includes the topics as listed above.
- All TFPP staff receive annual training on laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, intimate partner violence, as well as on human trafficking.

- All TFPP staff receive annual training on involving family members in the decision of minors to seek family planning services and on counseling minors on how to resist being coerced into engaging in sexual activities.

**Procedure:**

- The Reproductive and Women's Health Clinical Trainer develops a training plan for TFPP staff. The training plan addresses key requirements of the Title X program and priority areas, including how staff training needs are assessed.
- All staff involved in Family Planning are required to complete annual training on specific Family Planning policies and procedures that includes the topics as listed above. Staff are trained upon initial employment orientation and at least annually thereafter.
- Specific training verification forms are used, by the Metro/Regional Family Planning Administrator, to report completed trainings to Central Office program staff. Forms are available on *Sharepoint*: [Family Planning - Reports & Forms - Folders \(sharepoint.com\)](#) Semi-annual Reports are uploaded into Sharepoint Family Planning - [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant period.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: Family Planning - [1.7 Staff Training and Project Technical Assistance 2022.docx \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

# SERVICES & CLIENTS



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### CLIENT DIGNITY

Services must be provided in a manner which protects the dignity of the individual (42 CFR 59.5(a)(3)).

Policy Information:	Description:
Policy Title	Client Dignity
Effective Date	April 1, 2022
Revision Dates	March 11, 2022
Review Due Date	March 2023
References	<p>Providing Quality Family Planning Services: Recommendations from the Centers for Disease Control and Prevention and the U.S. Office of Population Affairs (QFP) (pages 4 and 24) <a href="https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html">https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html</a></p> <p>Code of Federal Regulations CFR 59.5(a)(3) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59.15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59.15</a></p>
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	March 21, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program process for ensuring compliance with the requirement that services provided through the Title X Project must be provided in a manner that protects the dignity of the individual.

#### Policy:

- The Tennessee Family Planning program provides services in a manner that is client-centered, culturally, and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.
- The Tennessee Family Planning program provides services in a manner that does not discriminate against any client based on religion, race, color, national origin, disability, age, sex, sexual orientation, gender identity, sex characteristics, number of pregnancies, or marital status.
- Client privacy will be protected during all aspects of their appointment/clinic encounter.
- "Client Bill of Rights" will be posted in the service sites, clearly visible to all clients, that outlines the client's rights and responsibilities. [Family Planning - Client Bill of Rights - Folders \(sharepoint.com\)](#)

- Every service site will conduct a client satisfaction survey once each calendar year for at least a period of five (5) working days using the prescribed satisfaction survey form. [Family Planning - CHS Policy 2.14 P0214\\_PatientSatisfaction.pdf - Folders \(sharepoint.com\)](#)
- Services will be provided in a client-centered, respectful, and culturally competent manner.
- Fees must be waived for individuals with family incomes above 100% of the FPL who, as determined by the service site project director, are unable, for good cause, to pay for family planning services (42 CFR 59.2).
- Tennessee Family Planning Program staff receive annual training in Client Dignity to meet the needs of our population.

**Procedure:**

- Tennessee Family Planning Program requires that the 'Client Bill of Rights' be shared with all clients (posted or given to each person). English and Spanish versions of the Patient Bill of Rights can be found on Sharepoint: [Insert Link here.](#)
- All service site directors are responsible for assuring that the Satisfaction Survey, for English and Spanish, is made available to patients visiting each site for a period of five (5) working days during the calendar year. Services offered on the days selected for the satisfaction survey shall be representative of the range of services provided by the Family Planning Program.
- All staff involved in Family Planning are required to complete training on specific Family Planning policies and procedures including Client Dignity.
- Specific training verification forms are used, by the Family Planning Administrator, to report completed trainings to Central Office program staff. Semi-annual Reports are uploaded into SharePoint: [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Central Office Family Planning Program staff monitors training records uploaded into Sharepoint to ensure compliance with this requirement.
- Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant period.
- The Family Planning Administrator (FPA), and key central office staff, are responsible for ensuring the clinic environment is welcoming (i.e., privacy, cleanliness of exam rooms, ease of access to service, fair and equitable charges for services including waiver of fees for "good cause," and language assistance).
- FPA will ensure that all family planning sites have a specific "good cause" waiver policy and procedure implemented. TDH policy is available on Sharepoint: [Family Planning - Good Cause Waiver 4.12\\_Charges for Patients Receiving Family Planning Services \(1\).pdf - Folders \(sharepoint.com\)](#)
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### NON-DISCRIMINATORY SERVICES

Services must be provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status (42 CFR 59.5 (a)(4)).

Policy Information:	Description:
<b>Policy Title</b>	Non-Discriminatory Services
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 22, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(a)(4) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 22, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program (TFPP) process for ensuring grantee and subrecipient compliance with the requirement that all services are provided without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.

#### Policy:

- **Title VI of the Civil Rights Act of 1964**, as amended ([42 USC § 2000d](#)), prohibits discrimination on the basis of race, color, or national origin [45 CFR 80](#).
- The United States Civil Rights Act of 1964 and Tennessee Code Annotated/T.C.A. 4-21-904 [Tenn. Code Ann. § 4-21-904](#) ensures the right to receive equal treatment and service opportunities regardless of race, color, national origin, or limited English proficiency. Title VI of the Civil Rights Act specifically prohibits discrimination in programs that are federally funded, and T.C.A. 4-21-904 specifically prohibits discrimination in programs that are State funded.
- Individuals receiving federal financial assistance, which can be distributed by state departments, will not face discrimination on the basis of race, color, national origin, sex, age, beliefs, or disability.
- TFPP services will be provided through the Title X-funded project without regard to religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.
- TFPP staff will be trained/informed of this requirement on an annual basis.

#### Procedure:



- To verify that all federal fund recipient state entities comply with Title VI of the Civil Rights act of 1964, all TDH staff are required to complete the annual web-based training “*Compliance with Title VI of the Civil Rights Act of 1964*” via the State of Tennessee’s Enterprise Resource Planning (ERP) system (EDISON).
- TCA S4-21-203 requires the Tennessee Human Rights Commission to review the Title VI monitoring and enforcement procedures, and
- Staff are trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### AVAILABILITY OF SOCIAL SERVICES

Projects must provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance (42 CFR 59.5 (b)(2)).

Policy Information:	Description:
<b>Policy Title</b>	Availability of Social Services
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 21, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (pages 4–20)  <a href="https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf">https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf</a></p> <p>Code of Federal Regulations 42 CFR 59.5 (b)(2) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rn=div6#se42.1.59_15</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 21, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program (TFPP) process for ensuring compliance with the requirement that the project provide for social services related to family planning including counseling, referral to and from other social and medical services agencies, and any ancillary services that may be necessary to facilitate clinic attendance, as needed.

#### Policy:

- The county/metro needs assessment will document the social service and medical needs of the community to be served.
- The needs assessment will document the ancillary services that are needed to facilitate clinic attendance, as well as identify relevant social and medical services available to help meet those needs.
- TFPP will collaborate with county/metro staff to develop and implement plans to address the related social service and medical needs of clients as well as ancillary services needed to facilitate clinic attendance.
- Each TFPP service site will have a process to refer clients to relevant social and medical services agencies (e.g., childcare agencies, transport providers, WIC programs).
- TFPP service sites will get signed written collaborative agreements with these other agencies when possible and if appropriate.
- TFPP staff and providers will document in the medical record when referrals were made, based on documented specific condition/issue.

**Procedure:**

- TFPP staff may locate up-to-date referral names and current contact information on *Sharepoint Family Planning Outside Referral Providers 2022.docx* ([sharepoint.com](#))
- The TFPP Regional/Metro FPA, along with healthcare experts and clinic medical staff, are responsible for the vetting of providers and referral resources by reviews and audits of these resources.
- Vetting includes:
  - Background check
  - Check Chamber Affiliations
  - Online research
    - AMA
    - Licensure Verification: [Tennessee Department of Health: Licensure Verification \(tn.gov\)](#)
    - Health Professionals Boards Disciplinary Actions: [Health Professionals Boards Disciplinary Actions \(tn.gov\)](#)
    - Abuse Registry: [Tennessee Department of Health: Abuse Registry \(tn.gov\)](#)
    - Health Care Facilities: [Search - Health Care Facilities \(tn.gov\)](#)
  - Reference Check
  - Experience in the field
  - Confirm compliance with OPA guidelines
  - Customer service feedback
- TFPP FPA confirms compliance as well as ensuring accurate information and contacts for all physicians, pharmacies, and care facilities.
- The TFPP builds upon existing relationships and establishes comprehensive collaboration among social service funders and providers, community and faith-based organizations, and advocates to ensure coordinated social service delivery through all phases of family planning and reproductive services.
- TFPP staff promotes and strengthens key community services/activities, such as childcare, elder care, foster care, mental health services, schools, housing, jobs, and transportation.
- TFPP staff enhance efforts to increase accessibility and reach to underserved, marginalized and vulnerable populations to provide needed social services.
- TFPP staff promote ongoing evaluation and continuous learning to advance social services efforts in achieving healthy community goals.
- Community Services and all Referral information/resources shall be reviewed/updated at least annually and clearly documented on the information/resource forms.
- Written collaborative agreements will be kept on file by the Regional/Metro FPA and posted on Sharepoint; [Family Planning - Collaborative Agreements and MOU's - Folders \(sharepoint.com\)](#)
- Written collaborative agreements shall be updated and/or renewed as needed.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### AVAILABILITY AND USE OF REFERRALS

Except as provided in 42 CFR 59.14(a) with respect to the prohibition on referrals for abortion as a method of family planning, projects must provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs (42 CFR 59.5(b)(8)).

Policy Information:	Description:
<b>Policy Title</b>	Availability and Use of Referrals
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 22, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs (pgs. 4–20)  <a href="https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf">https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf</a></p> <p>Code of Federal Regulations 42 CFR 59.5 (b)(8) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;gn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;gn=div6#se42.1.59_15</a></p>
<b>Approved by Signature</b>	<p>Danni Lambert, RN</p> <p>State Family Planning Director</p>
<b>Approved Date</b>	March 23, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program (TFPP) process for ensuring grantee and subrecipient compliance with the requirement for the coordination of effective patient referrals for other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal projects.

#### Policy:

- Family planning administrators shall ensure that all TFPP service sites have developed and implemented plans to coordinate with and refer clients to other services (as listed above) when appropriate.
- All TFPP service sites have processes for effective referrals to relevant agencies.
- TFPP FPA's and key central office staff work to establish new collaborative agreements and maintain established collaborations as appropriate.
- TFPP staff and providers document in the medical record when referrals were made based on documented specific condition/issue.

#### Procedure:

- TFPP staff may locate up to date referral names and contact information via *Sharepoint*: [Family Planning Outside Referral Provider file \(2021\)1.docx \(sharepoint.com\)](#)
- TFPP FPA's ensure the review and updating of referral information and resources is completed and documented as needed, at least annually, and uploaded into the appropriate *Sharepoint* file: [Family Planning - Resource Lists - Community and Provider - Folders \(sharepoint.com\)](#)
- TFPP central office staff and FPA's ensure the written collaborative agreements are reviewed and renewed as needed, at least annually, and uploaded on *Sharepoint*: [Family Planning - Collaborative Agreements and MOU's - Folders \(sharepoint.com\)](#).
- FPA will ensure that all TFPP service sites have a site-specific Community and Provider resource lists/handouts. Current resource lists are available on *Sharepoint*: [Family Planning - Resource Lists - Community and Provider - Folders \(sharepoint.com\)](#)
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### CLINICAL PROTOCOLS AND STANDARDS OF CARE

All grantees should ensure services provided within their project operate within written clinical protocols that are in accordance with nationally recognized standards of care, approved by the grantee, and signed by the physician responsible for the service site.

Policy Information:	Description:
<b>Policy Title</b>	Clinical Protocols and Standards of Care
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Providing Quality Family Planning Services: Recommendations from the Centers for Disease Control and Prevention and the U.S. Office of Population Affairs (QFP) (pages 1–40) <a href="https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html">https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html</a></p> <p>2022 Clinical Guidelines <a href="#">Family Planning - 2022 Family Planning Signature page &amp; Clinical Guidelines.pdf - Folders (sharepoint.com)</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program's process for ensuring compliance with the requirement that the Title X-funded project provides services in accordance with written clinical protocols aligned with nationally recognized standards of care.

#### Policy:

- All TFPP service sites will operate within written clinical protocols aligned with nationally recognized standards of care and signed by the medical director or physician responsible for the service site.

#### Procedure:

- Nationally recognized standards of care include but are not limited to: OPA, USPSTF, CDC, ACOG, ASCCP, MEC, SPR
- Clinical protocols are reviewed annually by RWH Clinical Trainer to ensure they are current and reflect current Federal and professional medical associations recommendations for each type of service as cited in the QFP, signed by the medical director and posted/uploaded in Sharepoint: [Family Planning - 2022 Clinical Guidelines - Folders \(sharepoint.com\)](#).
- The Family Planning Clinical Manual must be reviewed and signed annually by Physicians, Nurse Practitioners, Certified Nurse Midwives, Physician Assistants, Registered Nurses, Medical Assistants and Clinic Assistants providing clinical services in the Title X Family Planning Programs. Signature pages must be available for review during clinical site visits. Agencies with multiple sites should keep a copy of the signature page at each site or in the agency's local online



drive. Family Planning Administrators are asked to confirm obtaining annual staff and consulting physician signatures. [Title X Clinical Manual Review signature page 2022.pdf \(sharepoint.com\)](#)

- Assessing adherence to approved protocols through medical records reviews done biannually and during clinical review of medical charts, by the FPA, at service site visits.
- Client visit observations are also completed at a service site review using the Title X Program Review Tool.
- Protocols for services provided which are outside the scope of family planning must be developed through collaboration between the TDH, Community Health Services (CHS), and medical directors.
- All staff involved in Family Planning are required to complete the QFP training upon initial employment orientation and at least once per grant period thereafter.
- Specific training verification forms are used, by the Family Planning Administrator, to report completed trainings to RWH Clinical Trainer. Semi-annual Reports are uploaded into *Sharepoint* [Family Planning - Report Drop Boxes - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- RWH Clinical Trainer monitors training records uploaded into *Sharepoint* to ensure compliance with this requirement and that all guidelines are met.
- Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant cycle.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### PROVISION OF FAMILY PLANNING AND RELATED SERVICES

All projects must provide for medical services related to family planning (including consultation by a clinical services provider, examination, prescription and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, and necessary referral to other medical facilities when medically indicated and provide for the effective usage of contraceptive devices and practices. (42 CFR 59.5(b)(1)).

This includes but is not limited to emergencies that require referral. Efforts may be made to aid the client in finding potential resources for reimbursement of the referral provider, but projects are not responsible for the cost of this care.

Policy Information:	Description:
<b>Policy Title</b>	Provision of Family Planning and Related Services
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5 (b)(1) <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A#59.5">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A#59.5</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for ensuring compliance with the requirement that projects must provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and referral to other medical facilities when medically necessary, consistent with the prohibition on referral for abortion as a method of family planning in 42 CFR 59.14(a), and provide for the effective usage of contraceptive devices and practices.

#### Policy:

- TFPP clients served by the project, including adolescents, are provided the following services, as appropriate: a broad range of contraceptives, including natural family planning methods and other fertility awareness-based methods; pregnancy testing and counseling; services to assist with achieving pregnancy; basic infertility services; STD services; and preconception health services.
- Breast and cervical cancer screening will be available on-site or by referral.

#### Procedure:

- Age appropriate "initial/annual examinations" and "preventive health visits" are still encouraged in accordance with medical standards of care and clinical recommendations. TFPP visits have a

strong focus on risk reduction, health counseling, preventive services, and screening along with the provision of the core components of the QFP recommendations.

- TFPP clinical sites offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the site to promote holistic health and provide seamless care.
- All services listed in QFP are offered to TFPP clients, including adolescents as specified in clinical protocols.
- Description of collaborative agreements with relevant referral agencies including emergency care, HIV/AIDS care and treatment providers, infertility specialists, primary care, and chronic care management providers.
- TFPP staff and providers show compliance with this requirement by manual review, approval, and signatures; medical chart reviews and providing a list of formal agreements to the TDH/TFPP as part of the grant deliverables.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.
- Location of clinical protocols that document the services referenced in this policy are provided. [CHS/CLS/NURS - Nursing Protocols - Folders \(sharepoint.com\)](#)

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### RANGE OF FAMILY PLANNING METHODS

All Title X Projects must provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). ([42 CFR 59.5\(a\)\(1\)](#))

Policy Information:	Description:
<b>Policy Title</b>	Range of Family Planning Methods
<b>Effective Date</b>	October 4, 2021
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Providing Quality Family Planning Services: Recommendations from the Centers for Disease Control and Prevention and the U.S. Office of Population Affairs (QFP) Recommendations (pages 1–23)  <a href="https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html">https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html</a></p> <p>Code of Federal Regulations 42 CFR 59.5(a)(1)  <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for ensuring compliance with the requirement to provide a broad range of acceptable and effective family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents).

#### Policy:

- All clients will be provided a broad range of acceptable and effective family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents).
- The TFPP offers a wide range of FDA approved methods, including:
  - Male and female sterilization surgery
  - Hormonal IUDs
  - Copper IUD
  - Implant
  - Hormonal injection
  - Combined oral contraceptive pills
  - Progestin-only contraceptive pills
  - Hormonal patch
  - Vaginal ring

- Diaphragm
- Sponge
- Internal and external condoms
- Non-hormonal vaginal gel
- Spermicide
- Fertility-based awareness methods
- Emergency contraception pills

**Procedure:**

- All TFPP clinic sites must submit Exhibit C: Services Provided document [Family Planning - Exhibit C \(Services Provided\) DropBox - Folders \(sharepoint.com\)](#) on a quarterly basis (April, July, October, January) or with any change in services provided.
- Services provided by TFPP service sites, when viewed in its entirety, provide a broad range of acceptable and effective methods and services.
- Bi-annual medical record reviews demonstrate that clients are offered a broad range of acceptable and effective family planning methods and services.
- A review of the current stock of contraceptive methods demonstrates that a broad range of methods, including LARCs, are available on-site or by referral. All methods available on-site are in stock with no outdated contraceptive methods.
- The TFPP Formulary may be viewed on *Sharepoint*: [Family Planning - Formulary - Folders \(sharepoint.com\)](#)
- All services listed in QFP are offered to clients, including adolescents as specified in clinical protocols.
- The RWH Clinical Trainers ensures clinic protocols for contraceptive methods are reviewed and updated yearly.
- Method specific client information sheets are available and reviewed annually.
- TFPP ensures that a broad range of acceptable and effective family planning methods, including LARCs, are available through the service sites, optimally on-site, or by referral.
- Consent forms are required for procedures (IUD's and Implants). [Family Planning - Consent Forms - Folders \(sharepoint.com\)](#).
- Central Office Family Planning Program staff monitors to ensure compliance with this requirement as part of the Family Planning Program site visit at least once per grant period.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### DURATIONAL RESIDENCY

Services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician (42 CFR 59.5(b)(5)).

Policy Information:	Description:
<b>Policy Title</b>	Durational Residency
<b>Effective Date</b>	May 2022
<b>Revision Dates</b>	May 15, 2022
<b>Review Due Date</b>	May 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(b)(5) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	May 15, 2022

**Purpose:** The purpose of this policy is to describe how the TFPP will address the requirements mandated by Project Grants for Family Planning Services regulation [https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59#p-59.5\(b\)\(5\)](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59#p-59.5(b)(5)).

#### Policy:

- The Tennessee Family Planning Program shall ensure adherence to Office of Population Affairs/Title X federal regulation that *services must be provided without the imposition of any durational residency requirement or requirement that the client be referred by a physician.*

#### Procedure:

- The Tennessee Family Planning Program ensures compliance with all applicable laws and regulations. This procedure provides safeguards to ensure the Tennessee Family Planning Program complies with Office of Population Affairs Durational Residency requirement.
- The TFPP has a policy prohibiting the use of any residency requirement to access Title X services at any service site.
- TFPP service sites will maintain documentation to verify that services are provided without the imposition of any durational residency or physician referral requirements.
- TFPP Staff are trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- TFPP key central The grantee will monitor subrecipients and service sites to ensure compliance with this requirement during service site reviews.



- TFPP staff may access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### PREGNANCY TESTING AND DIAGNOSIS

Clients served in Title X-funded settings must be offered the opportunity to be provided information and counseling regarding each of the following options:

- Prenatal care and delivery;
- Infant care, foster care, or adoption; and
- Pregnancy termination.

If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling. ([42 CFR 59.5 \(a\)\(5\)](#))

Policy Information:	Description:
<b>Policy Title</b>	Pregnancy Testing and Diagnosis
<b>Effective Date</b>	October 4, 2021
<b>Revision Dates</b>	May 16, 2022
<b>Review Due Date</b>	May 16, 2023
<b>References</b>	<p>Code of Federal Regulations <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.5">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.5</a></p> <p>Providing Quality Family Planning Services <a href="https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf">https://opa.hhs.gov/sites/default/files/2020-10/providing-quality-family-planning-services-2014_1.pdf</a></p> <p>Title X of the Public Health Service Act, 42 U.S.C. 300, et seq. <a href="https://sgp.fas.org/crs/misc/RL33644.pdf">https://sgp.fas.org/crs/misc/RL33644.pdf</a></p> <p>Conscientious Objection to Abortion Counseling and Referral – 3.12 <a href="file:///C:/Users/dc60a12/Desktop/Policies%202022/GM_3.12_ConscientiousObjection.pdf">file:///C:/Users/dc60a12/Desktop/Policies%202022/GM_3.12_ConscientiousObjection.pdf</a></p>
<b>Approved by Signature</b>	<p>Danni Lambert, RN</p> <p>State Family Planning Director</p>
<b>Approved Date</b>	May 17, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for ensuring compliance with the requirement to provide pregnancy testing and diagnosis services to all clients in need of these services.

#### Policy:

- All TFPP service sites will provide pregnancy testing and diagnosis services to all clients in need of these services.
- Once a client served by a Title X project is medically verified as pregnant, the client will be provided a referral to appropriate providers of follow-up care is be made at the request of the client, as needed.

#### Procedure:

- TFPP staff offer the client information and counseling regarding each of the following options:

- Prenatal care and delivery;
  - Infant care, foster care, or adoption; and
  - Pregnancy termination.
- If requested to provide such information and counseling, TFPP staff provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling
- TFPP staff will provide information for both continuing and discontinuing pregnancy as desired by the patient
- The TFPP process for ensuring written clinical protocols regarding pregnancy testing and diagnosis are in accordance with the recommendations presented in the QFP, including reproductive life planning discussions and medical histories that include any coexisting conditions.
- Process for ensuring clients with a positive pregnancy test and who are in need of services who wish to continue the pregnancy receive initial prenatal counseling and are assessed regarding their social support.
- Process for ensuring clients with a negative pregnancy test who do not want to become pregnant are offered same-day contraception, if appropriate.
- The types of documentation that will be maintained to demonstrate referrals for abortion have only occurred in cases of medical emergencies, or in the case of incest or rape.
- The types of documentation that will be maintained to demonstrate that pregnancy testing, and diagnosis services are: 1) provided in accordance with QFP and 2) available and offered to all clients in need of these services.
- For detailed guidance please see Nursing Protocol 2.110 Pregnancy Test Conducted In A Family Planning Visit [CHS/CLS/NURS - 2.110 Pregnancy Test 02012022 signed.pdf - Folders \(sharepoint.com\)](#)
- TFPP/TDH ensures the conscience protections that apply to health care providers who refuse to perform, accommodate, or assist with certain health care services on religious or moral grounds.
  - Clinical staff who declare a conscientious objection to pregnancy termination will be required to immediately defer pregnancy all options counseling as prescribed by Title X to another clinician.
  - To comply with Title X of the Public Health Service Act, 42 U.S.C. 300, et seq., this policy applies to Local Health Department, Regional, and Central Office personnel.
  - Staff members who have a conscientious objection to abortion counseling and referral must ensure their direct supervisor is aware.
  - Abortion counseling and referral responsibilities will be deferred to another qualified staff member in person or via telehealth. Counseling the same day and by the same provider is preferred but should be within 1-2 business days.
- Grantee's process for monitoring subrecipients and service sites to ensure compliance with this requirement.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on [Sharepoint](#) at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#)). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### TELEHEALTH

Telehealth adoption in the U.S. has increased dramatically, and Title X supports the use of telehealth services as an option for their clients. Telehealth will help expand our capacity to provide services and increase community access to family planning services. Telehealth services support national efforts to achieve health equity by supporting the enhancement and expansion of telehealth services provided by Title X grantees.

Policy Information:	Description:
<b>Policy Title</b>	Telehealth
<b>Effective Date</b>	June 1, 2022
<b>Revision Dates</b>	May 10, 2022
<b>Review Due Date</b>	May 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(b)(1) Provide Medical Services Related to Family Planning <a href="https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21542.pdf">https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21542.pdf</a>  TN Code Annotated, Sec. 56-7-1002 & Sec. 56-7-1012, as amended by SB 2453 and HB 2655 (2022 session) (Accessed Apr. 2022) <a href="https://www.capitol.tn.gov/Bills/112/Bill/HB0620.pdf">https://www.capitol.tn.gov/Bills/112/Bill/HB0620.pdf</a> <a href="https://www.capitol.tn.gov/Bills/112/Bill/HB2655.pdf">https://www.capitol.tn.gov/Bills/112/Bill/HB2655.pdf</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	May 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for providing telehealth services in the Title X program. This policy will ensure that telehealth services are provided appropriately, and allow both clinical and nonclinical services (e.g., counseling and education) to be provided via telehealth methods. This policy will ensure compliance with Title X requirements.

**Policy:** Our policy is to provide telehealth as an option for family planning service delivery to enhance access in ways that are convenient, safe, and equitable for our clients. Every effort was made to capture the most recent policy language in Tennessee at the time it was reviewed.

#### Terminology

- **Telehealth.** For purposes of this policy and procedure, by telehealth we mean the discrete set of codes promulgated by the Centers of Medicare & Medicaid Services (CMS) that can either be provided in-person or by using an interactive audio and video telecommunications system that permits real-time communication between the clinician at the distant site and the beneficiary at the originating site.
- **Distant site.** We are the distant site when we deliver telehealth services to clients at a different location, including their home.

- **Originating site.** This is the site where the client is and may be when:
  - TFPP delivers telehealth services to a client at a different location, including their home – either of which would be the originating site, or
  - A clinician/specialist at a different location delivers telehealth services to a client at our clinic, making our clinic the originating site.

**Procedure:**

- **Sharepoint Telehealth Workflow:** [Family Planning - Telehealth Contraceptive Initiation & management workflow DL.pdf - Folders \(sharepoint.com\)](#) and [Family Planning - Telehealth work up flow sheet DL.pdf - Folders \(sharepoint.com\)](#)
- **Scheduling as Originating Site**
  - Specific Family Planning Telehealth laptop computers are available at all Family Planning clinic sites. When a TFPP is scheduled to receive telehealth family planning services at our , TFPP staff will provide a private space with camera, microphone, and privacy for the client to engage in the telehealth visit. The client will be advised to arrive 20 minutes prior to the appointment to set up and test the equipment. The client will be offered a knowledgeable staff member to accompany the visit to ensure a smooth telehealth experience. Prior to the visit, we will ensure that:
    - The provider has been provided with the medical records needed for the visit while adhering to the HIPAA Privacy rule governing “minimum necessary” when providing records/information.
    - TFPP staff are clear on their roles and responsibilities, especially around consent, documentation, and payment.
    - A TFPP appointment/referral has been entered into PTBMIS/EHR to close the loop and ensure that our provider has signed the referral notes/results
- **Scheduling as Distant Site**
  - When a client calls 1-833-690-0223 or visits <https://www.familyplanningtn.com/> to schedule an appointment they will be offered an in-person or telehealth visit. If the client chooses telehealth, staff will establish whether the reason for the visit and/or chief complaint is appropriate for a telehealth appointment. If the client’s needs or conditions change the client may need to be seen in person or seek urgent/emergent care. Staff will also ensure clients are clear on the expectations (i.e., must have a quiet place to take the telehealth visit, no multitasking) and the cost requirements as clients are often surprised that the cost/reimbursement for a telehealth visit is the same as an in-person visit. If client is a minor, follow TFPP confidentiality policies governing when minors seek family planning services. Staff will ask ““Do you have a smartphone, tablet, or desktop computer with camera and internet?” If clients have one of the three, they are considered “video-capable”. Staff will note video capability and document.
  - Client will be sent appointment confirmation by email or text, depending on client preference, with date/time of appointment with link for telehealth visit and instructions for connecting and an offer for a “test” telehealth visit.
- **Day of Visit**

- All clinic participants on the call will clearly introduce themselves to the client and wear or otherwise display their first and last names and credentials.
- Provider will:
  - Confirm the client's identity – picture on file, name, date of birth, etc.
  - Conduct intake, including the portions usually performed by reception staff for in-person visits
  - Advise the client how to make their copay when applicable.
  - Discuss back up plan for if the audio or video fails or the technology otherwise is not working for the client or the care team, including a number to call the client or for the client to call the provider
  - Obtain state required General Consent for Health Services [Family Planning - GENERAL CONSENT FOR HEALTH SERVICES.pdf - Folders \(sharepoint.com\)](#) and/or ACROBAT Sign PH1530 for Telehealth Use consent [Family Planning - Acrobat Sign PH1530 for Telehealth Use encrypted .pdf - Folders \(sharepoint.com\)](#)
  - As appropriate, obtain consent for the telehealth visit, depending on client's primary insurance:
 

Current State Laws & Reimbursement Policies <https://www.cchpca.org/>

    - Perform check-out for the client at the conclusion of the visit as per our procedure for in-person visits, including asking the client if they have any additional questions about their treatment plan and scheduling any follow-up or other visits
- **TFPP provider will:**
  - Document as per requirements for the given type of visit (e.g., Quick Start, Emergency Contraception, management/office visit, etc.)
  - Enter the appropriate billing code with modifiers, etc., depending on insurer
  - Communicate with client's preferred pharmacy or local Health Department for any prescriptions.
  - Follow up on all orders/referrals, etc.
  - As needed, ensure client is clear on co-payment/deductible amounts and how to pay
  - *Send telehealth follow-up survey to client per their preferences* English: [https://redcap.link/fpthsurvey\\_e](https://redcap.link/fpthsurvey_e), Spanish: [https://redcap.link/fpthsurvey\\_s](https://redcap.link/fpthsurvey_s)
- **HIPAA Privacy**
  - Clients will be advised to be in a private setting or use headset/ear buds and must identify for the provider(s) any other individuals that are present.
  - TFPP Provider(s) must be in a private space (e.g., exam room or office) or wear headset/ear buds to ensure conversations are private.
- **HIPAA Security**

All efforts have been made to ensure the security of client's protected health information (PHI) through use of HIPAA-compliant devices and telehealth platforms for both the client and clinical staff. All other contingencies have been made; the Security Officer has reviewed our policies and procedures to ensure that we are HIPAA-compliant and have mitigated any risks, including updating the security risk analysis with any changes resulting from the use of telehealth.
- **Monitoring & Training**



- Tennessee family planning central office staff monitors telehealth services to ensure compliance with Title X guidelines..
- TFPP Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the *TEAMS* Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Telehealth Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### COMPLIANCE WITH LEGISLATIVE MANDATES

Title X grantees must comply with applicable legislative mandates set out in the HHS appropriations act. Grantees must have written policies in place that address these legislative mandates.

Policy Information:	Description:
Policy Title	Compliance with Legislative Mandates
Effective Date	April 1, 2022
Revision Dates	March 2022
Review Due Date	March 2023
References	<a href="#">Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services</a> (42 CFR Part 59, October 2021) Title X Statute Section 1001: <a href="https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0_0.pdf">https://opa.hhs.gov/sites/default/files/2020-07/title-x-statute-attachment-a_0_0.pdf</a> Regulations- Family Planning Program Regulations 42CFR59 Grants for Family Planning Services - <a href="#">Subpart A</a> - Project Grants for Family Planning Services
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	March 10, 2022

**Purpose:** The purpose of this policy is to address the requirements mandated by the [Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services](#) (42 CFR Part 59, October 2021), which provides funding to the Tennessee Family Planning Program. The intent of this policy is to provide information on Title X Legislative mandates. Legislative mandates remain in effect until a new Final Rule is passed setting a new list of requirements.

**Policy:** The Tennessee Family Planning Program shall adhere to Office of Population Affairs/Title X federal legislative mandates through policy creation, implementation, and monitoring. The legislative mandates are available at: <https://opa.hhs.gov/grant-programs/title-x-service-grants/title-x-statutes-regulations-and-legislative-mandates>.

The current Legislative Mandates have been part of the Title X appropriations language for each of the last several years. These mandates remain in effect until a new Final Rule is passed and include the following:

“None of the funds appropriated in this Act may be made available to any entity under Title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary of Health and Human Services that it encourages family participation in the decision of minors to seek family planning services.”

Notwithstanding any other provision of law, no provider of services under Title X of the Public Health Service Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.

The Tennessee Family Planning Program services include administrative, clinical, counseling, and referral services necessary that ensure adherence to these requirements:

**Procedure:**

- The Tennessee Family Planning Program ensures compliance with all applicable laws and regulations. This procedure provides safeguards to ensure the Tennessee Family Planning Program complies with Office of Population Affairs/Title X Federal Legislative Mandates.
  - Family Planning providers encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health. (QFP page 13 , references 71-86) A pdf of the QFP is available on Sharepoint: [Family Planning - QFP.pdf - Folders \(sharepoint.com\)](#) and on the CDC website: [rr6304.pdf \(cdc.gov\)](#)
  - Counseling about family participation adhere to general counseling best practices outlined in QFP. The five principles for providing quality counseling are relevant when working with all clients, including teens. These quality principles include:
    - Establish and maintain rapport with the client
    - Assess the client's needs and personalize discussions accordingly
    - Work with the client interactively to establish a plan
    - Provide information that can be understood and retained by the client
    - Confirm client understanding
  - All cases of suspected child abuse/neglect or child sexual abuse shall be reported immediately to proper authorities. Tennessee's mandatory child abuse reporting law, [TCA 37-1-403](#) and [TCA 37-1-605](#).
- The Tennessee Family Planning Program's training plan [Training Plan Title X 2022.docx \(sharepoint.com\)](#) ensures mandatory annual training on *involving family members in the decision of minors to seek family planning services and Tennessee State laws requiring mandatory reporting of child abuse, child molestation, sexual abuse, rape, or incest*.
- All staff involved in Family Planning are required to complete annual training on specific Family Planning policies and procedures including *encouraging family participation in the decision of minors to seek family planning services and Tennessee State laws requiring mandatory reporting of child abuse, child molestation, sexual abuse, rape, or incest*. Staff are trained upon initial employment orientation and annually thereafter.
- All staff involved in Family Planning are required to complete annual training on specific Family Planning policies and procedures. Staff are trained upon initial employment orientation and annually thereafter.
- Specific training verification forms are used, by the Family Planning Administrator, to report completed trainings to Central Office program staff. Semi-annual Reports are uploaded into Sharepoint [Family Planning - Training Report DropBox - Folders \(sharepoint.com\)](#) by April 20th and October 20th. Each Family Planning service site maintains individual staff training documentation.
- Central Office Family Planning Program staff monitors training records uploaded into Sharepoint to ensure compliance with this requirement and that all guidelines are met
- Maintenance of site-specific training records is verified as part of the Family Planning Program site visit at least once per grant cycle.
- Family Planning staff will be trained on these policies upon initial onboarding. Updates or changes to these policies shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Family Planning staff can access policies virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

# CONFIDENTIALITY



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### CONFIDENTIALITY

Every project must have safeguards to ensure client confidentiality. Information obtained by project staff about an individual receiving services may not be disclosed without the individual's documented consent, except as required by law or as may be necessary to provide services to the individual, with appropriate safeguards for confidentiality. Concern with respect to the confidentiality of information may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or other similar reporting laws. Information may otherwise be disclosed only in summary, statistical, or other form that does not identify the individual (42 CFR 59.11).

<b>Policy Information:</b>	<b>Description:</b>
<b>Policy Title</b>	Confidentiality
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>Health Insurance Portability and Accountability Act (HIPAA) <a href="https://www.hhs.gov/hipaa/index.html">https://www.hhs.gov/hipaa/index.html</a></p> <p>TDH HIPAA Policies and Procedures Manual <a href="https://www.tn.gov/content/dam/tn/health/documents/TDH-HIPAA-Manual.pdf">https://www.tn.gov/content/dam/tn/health/documents/TDH-HIPAA-Manual.pdf</a></p> <p>HIPAA: Health Insurance Portability Accountability Act <a href="https://www.tn.gov/health/health-program-areas/hipaa.html">https://www.tn.gov/health/health-program-areas/hipaa.html</a></p> <p>HIPAA Hybrid Designation <a href="https://www.tn.gov/content/dam/tn/health/documents/HIPAA-Hybrid-Entity-Designation.pdf">https://www.tn.gov/content/dam/tn/health/documents/HIPAA-Hybrid-Entity-Designation.pdf</a></p> <p>Tennessee Code. Title 68 - Health, Safety and Environmental Protection Health Chapter 11 - Health Facilities and Resources Part 15 - Patient's Privacy Protection Act § 68-11-1503. <a href="https://law.justia.com/citations.html">https://law.justia.com/citations.html</a></p> <p>Confidentiality.</p> <p>Code of Federal Regulations 42 CFR 59.11 <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rn=div6#se42.1.59_15</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with the requirement to establish safeguards for ensuring client confidentiality. To establish clear expectations regarding all aspects of confidentiality.

**Policy:**

- TFPP requires that all service sites safeguard confidentiality.
- All staff will be informed (at least once per grant cycle) about policies related to preserving client confidentiality and privacy.
- Medical records system will have safeguards in place to ensure adequate privacy, security, and appropriate access to personal health information.
- The current "TDH Notice of Privacy Practices" shall be available in all offices of TDH.
- TDH will provide a copy of the current "TDH Notice of Privacy Practices" to any client requesting a copy. However, when TDH is a client's direct provider, TDH is required to give a copy of the notice to the client on the first date the client receives services. TDH must have each client who receives direct care from TDH to sign an acknowledgement of receiving the notice on their first date of service. If TDH cannot get a signed acknowledgement, then TDH will document the reason why one was not received in the client's record. Acknowledgement of receipts of the notice, and/or documentation of good faith effort to obtain written acknowledgement must be maintained for six years.  
[https://www.tn.gov/content/dam/tn/health/documents/Privacy\\_Pamphlet.pdf](https://www.tn.gov/content/dam/tn/health/documents/Privacy_Pamphlet.pdf)  
[https://www.tn.gov/content/dam/tn/health/documents/Privacy\\_Pamphlet\\_SP.pdf](https://www.tn.gov/content/dam/tn/health/documents/Privacy_Pamphlet_SP.pdf)
- General consent forms will be provided in a confidential manner and will note any limitations that may apply. [Family Planning - GENERAL CONSENT FOR HEALTH SERVICES.pdf - Folders \(sharepoint.com\)](#)

**Procedure:**

- Please see the TDH HIPAA Policies and Procedures Manual <https://www.tn.gov/content/dam/tn/health/documents/TDH-HIPAA-Manual.pdf> for full details.
- TFPP shall act in accordance with established TDH policy and procedures regarding the safeguarding of client PHI. All TDH employees will seek guidance from supervisors according to established TDH policy and procedures. TDH workforce members should consult with their Subsidiary Privacy Officer or the Department Privacy Officer in appropriate circumstances
- All TFPP and TDH employees are required to complete HIPAA training upon initial onboarding and annually thereafter.
- This annual training is administered, and compliance documented through the Edison employee learning management center.  
[https://hub.edison.tn.gov/oaam\\_server/login.do;jsessionid=T2bitFGrFww8vG-JxISi4LD\\_L3qAe-tFYoHaDYIpQ8NNDkMbIJUQ!926021466!1257625545](https://hub.edison.tn.gov/oaam_server/login.do;jsessionid=T2bitFGrFww8vG-JxISi4LD_L3qAe-tFYoHaDYIpQ8NNDkMbIJUQ!926021466!1257625545)

# COMMUNITY PARTICIPATION, EDUCATION, & PROJECT PROMOTION



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### COLLABORATIVE PLANNING AND COMMUNITY ENGAGEMENT

Title X grantees and subrecipient agencies must provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served; and by persons in the community knowledgeable about the community's needs for family planning services (42 CFR 59.5(b)(10)).

Policy Information:	Description:
Policy Title	Collaborative Planning and Community Engagement
Effective Date	April 1, 2022
Revision Dates	March 4, 2022
Review Due Date	March 2023
References	Code of Federal Regulations 42 CFR 59.5(b)(10) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for ensuring compliance with the requirement to establish a system for ensuring opportunities for participation to individuals who represent significant elements of the population served by the TFPP project, including participating in activities related to the development, implementation, and evaluation of the Title X project.

#### Policy:

- TFPP and TDH has established community engagement plans that ensure individuals who are broadly representative of the population be served, and those who are knowledgeable about the community's needs for family planning services, will participate in developing, implementing, and evaluating the Title X project.

#### Procedure:

- If the I&E Advisory Committee meets the requirements, it may serve in the Community Participation role, or a separate group can be identified, such as a public health advisory committee.
- The Community Participation Committee is supportive of the Title X program mission and work with similar populations.



- Community Participation Committee members can, but are not limited to:
  - Assist with program problem solving.
  - Offer feedback about the programs strengths and areas that need improvement.
  - Serve as advocates who can aid in increasing the understanding or need for the program within the community.
  - Offer feedback on Work Plans and annual action plans.
- The Community Participation Committee, or I&E Advisory Committee, if it meets the requirements, will meet once a year, or more as needed.
- The committee will review annual or quarterly data reports at the meeting and distribute them prior to the meeting. Meeting minutes will be kept.
- The FPA submits reports gathered by the Community Participation Committee (I&E Advisory Committee) as according to Report Due Dates and deliverable timeline (Attendance, discussion topics, minutes). Education Material Review form can be found on Sharepoint: [TFPP IE Advisory Committee Review Form 2022.docx \(sharepoint.com\)](#).
- I&E Committee documentation is submitted *at least annually* via Sharepoint: [Family Planning - I&E Committee Reports DropBox - Folders \(sharepoint.com\)](#)
- State director monitors Sharepoint to ensure all requirements are submitted appropriately and guidelines are met.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### SOCIAL MEDIA POLICY

Social media can include, but is not limited to web and mobile phone applications, curated blog posts, news, and story sharing sites, photo and video sharing sites, micro-blogging, etcetera, that can be used to enhance the community awareness and education efforts of the project. (42 CFR 59.5(b)(3))

Policy Information:	Description:
<b>Policy Title</b>	Social Media Policy
<b>Effective Date</b>	December 20, 2021
<b>Revision Dates</b>	
<b>Review Due Date</b>	December 20, 2022
<b>References</b>	42 CFR 59.5(b)(3)) <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A</a>  Tennessee Department of Health Communication Policy <a href="file:///C:/Users/dc60a12/Desktop/Policies%202022/21-5-Tennessee-Department-of-Health-Communication-Policy.pdf">file:///C:/Users/dc60a12/Desktop/Policies%202022/21-5-Tennessee-Department-of-Health-Communication-Policy.pdf</a>
<b>Approved by Signature</b>	<i>Danni Lambert</i> , RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for ensuring compliance with the requirement to provide for community information and education. Tennessee Department of Health (TDH) Office of Communication and Media

Relations is designated by the Commissioner of Health to direct and coordinate the provision of accurate, consistent, and impactful information concerning the department to both internal and external parties, in alignment with and support of the TFPP & TDH strategic goals.

#### Policy:

This policy is available for inspection and duplication in the Office of Communications and Media Relations and is posted online at <https://www.teamtn.gov/health/tdh-policies.html>

#### Procedure:

- Social media platforms may be used to facilitate communication, information sharing, collaboration, and engagement among users. TDH & TFPP employs social media tools as one of several means of serving, connecting, and interacting with Tennesseans to further the goals and mission of the TFPP.
- TFPP social media interactions, like other interactions with our clients and the public, are organized, consistent and accurate and follow TFPP and state of Tennessee policies for acceptable use.
- All TFPP/TDH social media platforms and accounts are administered and maintained by the Office of Communication and Media Relations. TDH has an overriding interest and responsibility to decide what is "spoken" on its behalf on social networking and social media sites. The TFPP

program work through the Office of Communication and Media Relations to determine whether the use of social media and/or social networking is appropriate for the particular circumstance to further their objectives and goals.

- Only individuals authorized by the TDH Director of Communication and Media Relations or his or her designee may publish content to the TDH website or state agency social computing technologies.
- All official TFPP communication through social media and social networking outlets will remain professional in nature and always be conducted in accordance with the TDH communication policy, practices, and expectations.
- Approval and Registration
  - All TDH social media sites shall be (1) approved by the director of the Office of Communication and Media Relations; (2) published using approved social networking platform and tools; and (3) administered by the director of the Office of Communication and Media Relations or his or her designee.
- Please find the entire Tennessee Department of Health Communication Policy at:  
<https://www.teamtn.gov/content/dam/teamtn/health/documents/policies/21-5-Tennessee-Department-of-Health-Communication-Policy.pdf>

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### COMMUNITY AWARENESS AND EDUCATION

Each family planning project must provide for community information and education programs. Community education should serve to achieve community understanding of the objectives of the project, make known the availability of services to potential clients, and encourage continued participation by persons to whom family planning services may be beneficial. (42 CFR 59.5(b)(3)). The community education program(s) should be based on an assessment of the needs of the community and should contain an implementation and evaluation strategy.

Policy Information:	Description:
<b>Policy Title</b>	Community Awareness and Education
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.5(b)(3) <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15">https://www.ecfr.gov/cgi-bin/text-idx?SID=c1cbd72e13f7230f1e8328fa52b57899&amp;mc=true&amp;node=sp42.1.59.a&amp;rgn=div6#se42.1.59_15</a>  Public Health Assessments <a href="https://www.tn.gov/health/health-program-areas/tennessee-vital-signs/redirect-tennessee-vital-signs/county-health-assessment.html">https://www.tn.gov/health/health-program-areas/tennessee-vital-signs/redirect-tennessee-vital-signs/county-health-assessment.html</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with the requirement to provide for community information and education programs.

#### Policy:

- TFPP ensures an established community education and service promotion plan that:
  - This plan purpose is to achieve community understanding of the objectives of the of the TFPP project, make known the availability of TFPP services to potential clients, and encourages continued participation by persons to whom family planning may be beneficial,
  - promotes the use of family planning among those with unmet need,
  - utilizes an appropriate range of methods to reach the community, and
  - includes an evaluation strategy.

#### Procedure:

- TFPP and health education staff make efforts to make services known to the target population of the Title X program. Including people from low-income families, people of color, and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.
- TFPP utilizes accepted, appropriate, valid, and reliable community assessment tools to determine community educational needs. Needs Assessment can be found on the TDH website.
- TFPP FPA's facilitate community awareness and access to program services,
- All FPA's must establish and implement community education and promotional activities. These can include, but are not limited to:
  - Participation in community events and activities to increase awareness of program services and distribute educational materials.
  - Implementation of social media as a community outreach and education tool.
  - Utilization the Social Media Outreach and Family Planning website(s).
  - Educational classes in schools, community groups and providers as requested and /or needed.
  - Education to other service agencies and institutions that can be of assistance in meeting program needs.
- Promotion activities and outreach are reviewed biannually by the FPA. This is to ensure responsiveness to the changing needs of the Family Planning needs of our communities. [Family Planning - Semi-annual FPOP Progress Reports 2022 - Folders \(sharepoint.com\)](#)
- FPA's are required to submit an annual Family Planning Outreach Plan (FPOP) to Family Planning director by April 15<sup>th</sup>. [Family Planning - Family Planning Outreach Plans - Folders \(sharepoint.com\)](#)
- State director monitors Sharepoint to ensure all requirements are submitted appropriately and guidelines are met.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

# INFORMATION & EDUCATION MATERIALS APPROVAL



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### MATERIALS REVIEW AND APPROVAL PROCESS

Title X grantees and subrecipient agencies are required to have a review and approval process, by an Advisory Committee, of all informational and educational (I&E) materials developed or made available under the project prior to their distribution (Section 1006(d)(2), PHS Act; 42 CFR 59.6(a)).

Policy Information:	Description:
Policy Title	I&E Materials Review and Approval Process
Effective Date	April 1, 2022
Revision Dates	March 4, 2022
Review Due Date	March 2023
References	Code of Federal Regulations 42 CFR 59.6(a) <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.6#p-59.6(a)">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.6#p-59.6(a)</a>
Approved by Signature	Danni Lambert, RN State Family Planning Director
Approved Date	March 10, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program process for ensuring compliance with the requirement to establish a review and approval process, by an Information & Education/Advisory (I&E) Committee, of Information & Educational materials (print or electronic) developed or made available under the Title X project, prior to their distribution.

#### Policy:

- All I&E materials developed or made available under the Title X project will be reviewed and approved by an I&E/Advisory Committee prior to their distribution.
- While I&E materials shared on social media must undergo an I&E Advisory Committee review and approval process, social media posts themselves do not require I&E Advisory Committee approval and are instead subject to the Tennessee Department of Health Communication Policy number 21-5. This policy is available for inspection and duplication in the Office of Communications and Media Relations and is posted online at <https://www.teamtn.gov/health/tdh-policies.html>

**Procedure:** The Tennessee Family Planning Program requires that each Region, Metro, or contracted Family Planning Administrator establishes and implements a materials review and approval process for all their service sites.

**Process:** The Family Planning Administrator (FPA) shall ensure the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an



I&E/Advisory Committee prior to their distribution, to ensure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X. The program shall not disseminate any materials which are not approved by the I&E/Advisory Committee.

- The FPA is responsible for establishing and maintaining an Information and Education/Advisory Committee (I&E) as follows:
  - *Size* - The committee shall consist of no fewer than five members and up to as many members as the FPA determines necessary.
  - *Composition* - The committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, sex characteristics, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).
  - *Function* - In reviewing materials, the I&E/Advisory committee shall:
    - Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed.
    - Consider the standards of the population or community to be served with respect to such materials.
    - Review the content of the material to ensure that the information is factually correct, medically accurate, culturally, and linguistically appropriate, inclusive, and trauma informed.
    - Determine whether the material is suitable for the population or community to which it is to be made available; and
    - Establish a written record of its determinations.
  - *Criteria* - Documentation and reports utilized by the I&E/Advisory Committee members.
    - Meeting Agenda
    - Meeting Minutes
    - Documentation of Work Plan review/approval
    - Roster of committee members and demographics- [Family Planning - Demographic Information Sheet Fillable.pdf - Folders \(sharepoint.com\)](#)
    - Sample of each reviewed handout, brochure, website, or poster
    - Materials review form- [Family Planning - TDH IE Material Review Committee Fillable Form.pdf - Folders \(sharepoint.com\)](#)
    - List of materials reviewed including dates reviewed and approved via the *I&E Materials Inventory Log*- [I E materials inventory log 2020.xlsx \(sharepoint.com\)](#)
    - Any education/updates presented to your committee
  - *Frequency* - I&E/Advisory committee shall convene as needed to review materials, but it must meet *at least annually*
- Tennessee family planning state program director monitors FPA's and service sites to ensure compliance with this requirement.

- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### ADVISORY COMMITTEE MEMBERSHIP

Each Title X grantee must have an Advisory Committee of at least five members, except that the size provision may be waived by the Secretary for good cause shown (42 CFR 59.6(b)(1)). An Advisory Committee must review and approve informational and educational (I&E) materials developed or made available under the project prior to their distribution to ensure that the materials are suitable for the population and community for which they are intended and to ensure their consistency with the purposes of Title X (Section 1006(d)(1), PHS Act; 42 CFR 59.6(a)).

Policy Information:	Description:
<b>Policy Title</b>	I&E Advisory Committee Membership
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.6(b)(1) and 42 CFR 59.6(a) <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.6#p-59.6">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.6#p-59.6</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Programs process for ensuring grantee and subrecipient compliance with the requirement to establish a system for meeting membership size requirements for any I&E Advisory Committee that will review and approve an I&E material developed or made available by the grantee under the Title X project, prior to their distribution.

#### Policy/Procedure:

- Tennessee Family Planning Programs I&E Materials Review/Advisory committee serves the dual purpose of Advisory and Materials Review duties.
- This has been prior approved by the Office of Population Affairs and Title X. Please see TFPP Policies: 5.1, 5.2, 5.3.
- These policies may be accessed virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### GRANTEE OVERSIGHT FOR MATERIALS REVIEW

The grantee may delegate I&E functions for the review and approval of materials to sub-recipient agencies; however, the oversight of the I&E review process rests with the grantee.

Policy Information:	Description:
<b>Policy Title</b>	Grantee Oversight for Materials Review
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal regulations t Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, A Rule by the Health and Human Services Department <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A#59.5">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A#59.5</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with the requirement that the TFPP provides oversight for the materials review and approval process.

#### Policy:

- TFPP ensures that all clinic and service sites adhere to all Title X I&E materials review and approval requirements.

#### Procedure:

- The Tennessee Family Planning Program requires that each Region, Metro, or contracted Family Planning Administrator establishes and implements a materials review and approval process for all their service sites.
  - The FPA is responsible for establishing and maintaining an Information and Education/Advisory Committee (I&E).
- Tennessee family planning state program director monitors FPA's and service sites to ensure compliance with this requirement.
- FPA's are required to submit/upload required I&E Advisory documentation to State Family Planning Director and/or *Sharepoint*: [Family Planning - I&E Committee Reports DropBox - Folders \(sharepoint.com\)](#) at least annually by April 1<sup>st</sup>.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.

- Staff can access this policy virtually on *Sharepoint* at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual.

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### ADVISORY COMMITTEE RESPONSIBILITY FOR MATERIALS REVIEW

An Advisory Committee(s) may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate project staff; however, final responsibility for approval of informational and educational (I&E) materials rests with an Advisory Committee.

Policy Information:	Description:
<b>Policy Title</b>	Advisory Committee Responsibility for I&E Materials Review
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 42 CFR 59.6 <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A#59.6">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A#59.6</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Program process for ensuring compliance with the requirement to review the factual, technical, and clinical accuracy of all I&E materials developed or made available under the Title X project.

**Policy:** The Tennessee Family Planning Program will ensure that an appropriate project staff review the factual, technical, and clinical accuracy of all I&E materials developed or made available to the Title X project.

- This function is delegated to the Reproductive Women's Health (RWH) Clinical Trainer, a key Tennessee Family Planning Program project staff member.
- The I&E Committee may delegate responsibility for the review of the factual, technical, and clinical accuracy to appropriate local project staff, Advanced Practice Nurse or higher.
- Final responsibility for approval of the I&E materials rests with the Committee.

**Procedure:**

- In reviewing materials, the I&E Advisory Committee(s) shall:
  - Consider the educational, cultural, and diverse backgrounds of the individuals to whom the materials are addressed
  - Consider the standards of the population or community to be served with respect to such materials



- Review the content of each material to assure that the information is factually correct, medically accurate, culturally, and linguistically appropriate, inclusive, and trauma-informed
- Determine whether a material is suitable for the population or community to which it is to be made available
- Establish a written record of its determinations Tennessee family planning state program director monitors FPA's and committee activities to ensure compliance with this requirement
- I&E Committee documentation is submitted *at least annually* via Sharepoint: [Family Planning - I&E Committee Reports DropBox - Folders \(sharepoint.com\)](#)
- State director monitors Sharepoint to ensure all requirements are submitted appropriately and guidelines are met
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### I & E ADVISORY COMMITTEE REQUIREMENTS

In reviewing materials, an informational and educational (I&E) Advisory Committee(s) must:

- Consider the educational, cultural, and diverse backgrounds of the individuals to whom the material is addressed
- Consider the standards of the population or community to be served with respect to such materials
- Review the content of the material to assure that the information is factually correct, medically accurate, culturally, and linguistically appropriate, inclusive, and trauma-informed
- Determine whether the material is suitable for the population or community to which it is to be made available
- Establish a written record of its determinations (Section 1006(d), PHS Act; 42 CFR 59.6(b))

Policy Information:	Description:
<b>Policy Title</b>	<b>I&amp;E Advisory Committee Requirements</b>
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>CDC Health Literacy Resources  <a href="https://www.cdc.gov/healthliteracy/developmaterials/testing-messages-materials.html">https://www.cdc.gov/healthliteracy/developmaterials/testing-messages-materials.html</a> <a href="https://www.cdc.gov/healthliteracy/culture.html">https://www.cdc.gov/healthliteracy/culture.html</a></p> <p>Code of Federal Regulations 42 CFR 59.6(b) <a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.6#p-59.6(b)">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-59/subpart-A/section-59.6#p-59.6(b)</a></p> <p>Tips for Using a Trauma-Informed Lens to Develop or Select I&amp;E Materials  <a href="https://rhntc.org/resources/tips-using-trauma-informed-lens-develop-or-select-ie-materials">https://rhntc.org/resources/tips-using-trauma-informed-lens-develop-or-select-ie-materials</a></p>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe the Tennessee Family Planning Programs process for ensuring grantee and subrecipient compliance with the requirements for an I&E/Advisory Committee.

#### Policy:

- All family planning and reproductive health materials, print and electronic, that The Tennessee Family Planning Program and service sites make available to clients and potential clients must go through the I&E materials review process.
- Tennessee Family Planning Program materials need to be reviewed regardless of whether they were created in-house, by a company that creates health education materials, or by the Centers for Disease Control and Prevention (CDC) or another government agency.

- An I&E/Advisory Committee will determine whether a material is suitable for the target population or community through a documented review and approval process that includes:
  - Consideration of the educational, cultural, and diverse backgrounds of the individuals to whom the materials are addressed
  - Consideration of the standards of the population or community to be served
  - Assessment of whether material content is factually correct and medically accurate, culturally, and linguistically appropriate, inclusive, and trauma-informed

**Procedure:**

- The Family Planning Administrator (FPA) reviews local and FPAR data to identify demographics of current, and potential clients, and recruits I&E Advisory Committee members who reflect these demographics.
- All committee members receive an overview of the expectations of the Title X grant and an overview of Tennessee family planning services provided. The FPA may utilize the following resources to educate committee members:
  - Reproductive Health National Training Center (RHNTC) <https://rhntc.org/about>
  - Title X Family Planning Program [https://opa.hhs.gov/sites/default/files/2021-01/HHS-OPA-Title-X-Family-Planning-Program\\_0.pdf](https://opa.hhs.gov/sites/default/files/2021-01/HHS-OPA-Title-X-Family-Planning-Program_0.pdf)
  - Providing Quality Family Planning Services (QFP) <http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>
- The local FPA hosts at least 1 face to face (in person or virtual) committee meeting annually. The committee may meet on an as needed basis to review new educational and promotional materials before the material is released for use.
  - Orientation should be provided for new committee members.
  - FPA should provide updates to committee members between meetings by email, phone calls or other forms of communication
  - Interim meetings, meetings for new material review and new member orientation, may be held via email communication, TEAMS, phone, or in-person.
- The annual meeting will, at a minimum, include:
  - Title X Family Planning discussion and updates.
  - The annual work plan review and discussion.
  - Family planning outreach plan review; and
  - Education and promotional materials reviewed/approved by committee members.
- Process for conducting I&E material reviews.
  - The FPA conducts an initial material review to ensure that the materials align with the educational, cultural, and diverse backgrounds of their client population.
  - The FPA provides committee with guidance on how to ensure that I&E materials are culturally and linguistically appropriate, inclusive, and trauma informed.
  - All client education or information materials must be reviewed, by each committee member, and a consensus of approval must be reached before the materials are provided to clients or the community.
- Criteria and review tools that I&E Advisory Committee members may use to ensure that the materials are suitable for the population and community for which they are intended include, but are not limited to;
  - Education Materials Review Forms located on Sharepoint: [Family Planning - TDH IE Material Review Committee Fillable Form.pdf - Folders \(sharepoint.com\)](#), [I E materials inventory log 2020.xlsx \(sharepoint.com\)](#),
  - A recommended tool for reading level assessment may be found at the Readability Formulas link: <https://readabilityformulas.com/free-readability-formula-tests.php>

- If committee members are not proficient in language being reviewed, the FPA may access translation services via a state contract with the *UT Foreign Language Institute*.
- All Family Planning materials must be reviewed and approved by the committee before distribution.
- I&E Committee documentation is submitted *at least annually* via Sharepoint: [Family Planning - I&E Committee Reports DropBox - Folders \(sharepoint.com\)](#)
- State director monitors Sharepoint to ensure all requirements are submitted appropriately and guidelines are met
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual

# ADDITIONAL ADMINISTRATIVE REQUIREMENTS



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### FACILITIES AND ACCESSIBILITY OF SERVICES

Title X clinics must have written policies that are consistent with the HHS Office for Civil Rights policy document, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 4, 2003) (HHS Grants Policy Statement 2007, II-23).

Projects may not discriminate based on disability and, when viewed in their entirety, facilities must be readily accessible to people with disabilities (45 CFR 84).

Policy Information:	Description:
<b>Policy Title</b>	Facilities and Accessibility of Services
<b>Effective Date</b>	November 6, 2002
<b>Revision Dates</b>	December 6, 2019
<b>Review Due Date</b>	March 2023
<b>References</b>	<p>HHS Office for Civil Rights <a href="https://www.hhs.gov/ocr/index.html">https://www.hhs.gov/ocr/index.html</a></p> <p>Providing Quality Family Planning Services: Recommendations from the Centers for Disease Control and Prevention and the U.S. Office of Population Affairs (QFP) (page 24) <a href="https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html">https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html</a></p> <p>Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons <a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html">https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-vi/index.html</a></p> <p>CDC Health Literacy Resources <a href="https://www.cdc.gov/healthliteracy/developmaterials/testing-messages-materials.html">https://www.cdc.gov/healthliteracy/developmaterials/testing-messages-materials.html</a></p> <p>TENNESSEE DEPARTMENT OF HEALTH POLICY REGARDING EQUAL ACCESS FOR PERSONS WITH DISABILITIES <a href="https://www.tn.gov/content/dam/tn/health/program-areas/title-vi/TDH-ADA-Policy-2020A.pdf">https://www.tn.gov/content/dam/tn/health/program-areas/title-vi/TDH-ADA-Policy-2020A.pdf</a></p> <p>Title VI Limited English Proficiency (LEP) Patient Services - 2.16 <a href="https://www.tn.gov/content/dam/tn/health/program-areas/title-vi/TDH-General-Administration.pdf">https://www.tn.gov/content/dam/tn/health/program-areas/title-vi/TDH-General-Administration.pdf</a> and State of TN Administrative Policies and Procedures: <a href="file:///C:/Users/dc60a12/Desktop/Policies%202022/Policy%201.04%20TDHS%2">file:///C:/Users/dc60a12/Desktop/Policies%202022/Policy%201.04%20TDHS%2</a></p>

<b>Policy Information:</b>	<b>Description:</b>
	<a href="#">0Limited%20English%20Proficiency%20Guidelines__Signed_020419_Posting.pdf</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program's process for ensuring compliance with the requirement that clinic sites are readily accessible to individuals with physical disabilities or language barriers and ensure meaningful communication with persons that experience Limited English Proficiency.

**Policy:**

- The Tennessee Department of Health is committed to providing persons with disabilities an equal opportunity to participate and equally effective communication when accessing the Department's programs, services, activities, and other benefits available to the public.
- Language translation services will be readily provided, at no cost to clients, when needed.
- Individuals with disabilities will have access to services at grantee and subrecipient sites.
- Title VI of the Civil Rights Act of 1964 provides that no person shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity that receives federal financial assistance. Several programs in the Tennessee Department of Health (TDH) receive federal financial assistance from federal agencies including the Department of Health and Human Services, and the United States Department of Agriculture; therefore, TDH and the TFPP complies with the provisions of Title VI. This policy deals specifically with assuring that persons with Limited English Proficiency (LEP) receive the language assistance necessary to afford them meaningful access to these public health services

**Procedure:**

- Language assistance will be provided through use of competent bilingual staff, staff interpreters, contracts or formal arrangements with organizations providing interpretation or translation services, or technology and telephonic interpretation services. Please see: [https://www.tn.gov/content/dam/tn/human-services/documents/Policy%201.04%20TDHS%20Limited%20English%20Proficiency%20Guidelines\\_\\_Signed\\_020419\\_Posting.pdf](https://www.tn.gov/content/dam/tn/human-services/documents/Policy%201.04%20TDHS%20Limited%20English%20Proficiency%20Guidelines__Signed_020419_Posting.pdf) for a detailed procedure.
- Language translation services will be readily provided, at no cost to clients, when needed.
- Informational poster, in multiple languages, is clearly posted at each TFPP site.
- Title VI – Civil Rights Non-Discrimination Policy poster is required by TDH to be clearly posted in all sites.
- TDH conducts a regular review of the language access needs of our service population, as well as update and monitor the implementation of this policy and these procedures, as necessary, on an ongoing basis,
- TDH assesses changes in demographics, types of services or other needs that may require reevaluation of this policy and its procedures.
- This policy applies to the TFPP staff and its contractors and subrecipients which provide services or benefits to the public, regardless of whether the entity receives federal funds.
- All Family Planning staff will be trained on these policies upon initial onboarding.
- All staff contractors and subrecipients required to complete annual Title VI Training.
  - All state governmental entities that are recipients of Federal financial assistance comply with the requirements of Title VI of the Civil Rights Act of 1964 pursuant to

the State of Tennessee Public Acts, 2009 Public Chapter No. 437. Title VI prohibits discrimination based on race, color, or national origin in programs and activities receiving Federal financial assistance.

- To identify populations that may be in need of culturally competent care, Health Councils exist in all 95 counties with TDH directly supporting those councils. Each county brings together diverse stakeholders to look at data, identify disparities, and select priority areas to work on. Building on local expertise and community engagement and with focus on vulnerable populations.
- Family Planning staff can access policies virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual



## TENNESSEE FAMILY PLANNING PROGRAM POLICY AND PROCEDURES

### HUMAN SUBJECTS CLEARANCE (RESEARCH)

Research conducted within Title X projects may be subject to Department of Health and Human Services regulations regarding the protection of human subjects (45 CFR Part 46). The grantee/sub-recipient should advise OPA in writing of any research projects that involve Title X clients.

Policy Information:	Description:
<b>Policy Title</b>	Human Subjects Clearance (Research)
<b>Effective Date</b>	April 1, 2022
<b>Revision Dates</b>	March 4, 2022
<b>Review Due Date</b>	March 2023
<b>References</b>	Code of Federal Regulations 45 CFR Part 46 <a href="https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46">https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46</a> Tennessee Department of Health Institutional Review Board <a href="https://www.tn.gov/health/health-program-areas/tennessee-department-of-health-institutional-review-board.html">https://www.tn.gov/health/health-program-areas/tennessee-department-of-health-institutional-review-board.html</a>
<b>Approved by Signature</b>	Danni Lambert, RN State Family Planning Director
<b>Approved Date</b>	March 10, 2022

**Purpose:** The purpose of this policy is to describe Tennessee Family Planning Program process for ensuring compliance with the requirement that grantee and subrecipients have a system in place for advising OPA in writing of any research projects that involve Title X clients.

#### Policy:

Notification will be given in writing to OPA regarding any research projects that involve Title X clients.

#### Procedure:

- TFP advises OPA in writing of any research projects that involve Title X clients.
- The TDH gives assurance that it complies with the U.S. Department of Health and Human Services regulations for the protection of human research subjects. All information and documents are available at [www.IRBnet.org](http://www.IRBnet.org). The TDH IRB is convened monthly.
  - IRB administration may be reached at [TDH-IRB.Health@tn.gov](mailto:TDH-IRB.Health@tn.gov) or 615-253-2557.
- Staff will be trained on this policy upon initial onboarding. Updates or changes to this policy shall be provided, as needed, via memo and/or the TEAMS Monthly FPA virtual conference call.
- Staff can access this policy virtually on Sharepoint at: [Family Planning - Family Planning Policy & Procedure - Folders \(sharepoint.com\)](#). A paper version is in the Family Planning Administrative Manual



# Abortion Resource List

## **Tennessee**

- Carafem – Nashville Metro (Mt Juliet, TN)
  - <https://carafem.org/location/carafem-health-center-nashville/>
  - 877-708-2423
- Planned Parenthood
  - <https://pptnm.org>
  - 866-711-1717 (Option “2” for scheduling.)
  - See back of page for more info.
  - Locations in Nashville, Knoxville\*, and Memphis.
- Knoxville Center for Reproductive Health (Knoxville, TN)
  - <http://kcrh.com>
  - 865-637-3861
  - 800-325-5357
- Choices (Memphis, TN)
  - <https://memphischoices.org/>
  - 901-274-3550

## **Alabama**

- Alabama Women’s Center for Reproductive Alternatives (Huntsville, AL)
  - <http://alabamawomensclinic.com/>
  - 256-536-2231
- Reproductive Health Services of Montgomery (Montgomery, AL)
  - <http://rhs4choice.com>
  - 334-834-4988
  - 800-277-0156
- West Alabama Women’s Center (Tuscaloosa, AL)
  - <https://alabortionclinic.com/>
  - 205-556-2026
  - 800-616-2383

## **Georgia**

- A Preferred Women’s Health Center
  - <http://apwhc.vom>
  - 888-562-7415
  - Locations in Forest Park, GA and Augusta, GA.
- Atlanta Comprehensive Wellness Clinic
  - <http://acwcmidtownabortionclinic.vom>
  - 770-212-9660
- Atlanta Women’s Medical Center
  - <http://atlantawomensmedicalcenter.com>
  - 404-257-0057
- Carafem – Atlanta
  - <https://carafem.org/location/carafem-health-center-atlanta/>
  - 877-708-2423
- Feminist Women’s Health Center (Atlanta, GA)
  - <http://feministcenter.org>
  - 404-728-7900
  - 800-877-6013
- Old National Gynecology (College Park, GA)
  - <http://www.atlanta-abortion-clinic.com/>
  - 770-991-7552
- Savannah Medical Clinic (Savannah, GA)
  - <http://savannahmedicalclinic.com>
  - 912-236-1603
- Southeast Dekalb GYN (Decatur, GA)
  - <https://www.southeastdekalbgyn.com/>
  - 404-284-3200
- Summit Medical Center (Atlanta, GA)
  - <http://summitcenters.com>
  - 800-537-2985

Resources compiled from the National Abortion Federation at <https://prochoice.org>.

REVISED 5/18/2022

**Nash, Elizabeth (HHS/OASH)**

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**Subject:** FW: Program Review Final Report

**From:** Reed, Tisha (OS/OASH)

**Sent:** Wednesday, October 19, 2022 4:45 PM

**To:** Danni Lambert <[Danni.Lambert@tn.gov](mailto:Danni.Lambert@tn.gov)>

**Cc:** [denise.werner@tn.gov](mailto:denise.werner@tn.gov); Crissy Hartsfield <[Crissy.Hartsfield@tn.gov](mailto:Crissy.Hartsfield@tn.gov)>; Margolis, Amy (HHS/OASH) <[Amy.Margolis@hhs.gov](mailto:Amy.Margolis@hhs.gov)>; Harvey, Alissa (OS/OASH) <[Alissa.Harvey@hhs.gov](mailto:Alissa.Harvey@hhs.gov)>; Merchant, Shenena (OS/OASH) <[Shenena.Merchant@hhs.gov](mailto:Shenena.Merchant@hhs.gov)>; Fuller, Robin (HHS/OASH) <[Robin.Fuller@hhs.gov](mailto:Robin.Fuller@hhs.gov)>

**Subject:** Program Review Final Report



Title X VPR



QFP Clinical



TN VPR Final

Report Cover Let... Assessment Che... Report\_10.19.20...

Danni,

It is so great to have you back! Please review this report and let me know if you have any questions.

- The Tennessee Department of Health plan for improvement addressing the one finding is due November 18, 2022. Please let me know if a different deadline is required.
- The final report detailing the actions taken from the plan for improvement is due January 17, 2022.

Please upload both items as a grant note in GrantSolutions using grant #FPHPA006553.

One update—the area of improvement was with regard to services to male patients. Please review that section in the report carefully. Let me know if you need any technical assistance.

One other action item, if you remember from the exit interview, Karen was concerned about patient counseling once the new state law was enacted on August 25<sup>th</sup>. In the end, it was determined that Tennessee Department of Health was compliant and did meet expectations as of the date of the Program Review. That said, please update us on the policy changes in response to enactment of *Tenn. Code Ann. § 39-15-213*.

Congratulations on such a wonderful review and leading a strong Title X program. We appreciate all the work you and your team do every day to provide sexual and reproductive health services to people in Tennessee.

**Tisha Reed, MA**

*Pronouns: she/her*

**Clifton Strengths: Arranger, Strategic, Positivity, Achiever, Relator**

Public Health Analyst

Title X Project Officer

Office of Population Affairs

Need to chat? Click [here](#) to schedule.

**Email:** [tisha.reed@hhs.gov](mailto:tisha.reed@hhs.gov)

**Desk:** (240) 453-6162

<https://opa.hhs.gov/>





DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Office of the Secretary

Notice of Award

**Tab V**

Award# 1 FPHPA006553-01-00  
FAIN# FPHPA006553  
Federal Award Date: 03/24/2022

**Recipient Information**

**1. Recipient Name**

Health, Tennessee Dept Of  
710 James Robertson Pkwy 64 Andrew Johnson  
Tower  
Family Health and Wellness  
Nashville, TN 37243-0001

**2. Congressional District of Recipient**  
00

**3. Payment System Identifier (ID)**

1626001445A1

**4. Employer Identification Number (EIN)**

626001445

**5. Data Universal Numbering System (DUNS)**

172636268

**6. Recipient's Unique Entity Identifier**

**7. Project Director or Principal Investigator**

Ms. Danni Lambert  
Family Planning Program Director  
danni.lambert@tn.gov  
615-741-0224

**8. Authorized Official**

Dr. Lisa Piercey  
Commissioner  
Lisa.Piercey@tn.gov  
615-741-2974

**Federal Agency Information**

OASH Grants and Acquisitions Management Division

**9. Awarding Agency Contact Information**

Miss Robin Fuller  
Senior Grants Management Specialist  
robin.fuller@hhs.gov  
240-453-8830

**10. Program Official Contact Information**

Ms. Tisha Reed  
Public Health Analyst/Title X Project Officer  
tisha.reed@hhs.gov  
240-453-6162

**Federal Award Information**

**11. Award Number**

1 FPHPA006553-01-00

**12. Unique Federal Award Identification Number (FAIN)**

FPHPA006553

**13. Statutory Authority**

Title X of the Public Health Service Act, Section 1001 (42 U.S.C. § 300)

**14. Federal Award Project Title**

Title X Family Planning Services

**15. Assistance Listing Number**

93.217

**16. Assistance Listing Program Title**

Family Planning Services

**17. Award Action Type**

New

**18. Is the Award R&D?**

No

**Summary Federal Award Financial Information**

**19. Budget Period Start Date** 04/01/2022 - **End Date** 03/31/2023

**20. Total Amount of Federal Funds Obligated by this Action** \$7,108,750.00

20a. Direct Cost Amount \$12,656,373.00

20b. Indirect Cost Amount \$250,000.00

**21. Authorized Carryover** \$0.00

**22. Offset** \$0.00

**23. Total Amount of Federal Funds Obligated this budget period** \$0.00

**24. Total Approved Cost Sharing or Matching, where applicable** \$5,797,623.00

**25. Total Federal and Non-Federal Approved this Budget Period** \$12,906,373.00

**26. Project Period Start Date** 04/01/2022 - **End Date** 03/31/2027

**27. Total Amount of the Federal Award including Approved  
Cost Sharing or Matching this Project Period** Not Available

**28. Authorized Treatment of Program Income**

OTHER (See REMARKS)

**29. Grants Management Officer - Signature**

Dr. Scott Moore  
OASH Grants Management Officer

**30. Remarks**

See Remarks (continuation)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Award

Award# 1 FPHPA006553-01-00

FAIN# FPHPA006553

Federal Award Date: 03/24/2022

**Recipient Information**

**Recipient Name**

Health, Tennessee Dept Of  
710 James Robertson Pkwy 64 Andrew Johnson  
Tower  
Family Health and Wellness  
Nashville, TN 37243-0001

**Congressional District of Recipient**

00

**Payment Account Number and Type**

1626001445A1

**Employer Identification Number (EIN)**

626001445

**Data Universal Numbering System (DUNS)**

172636268

**Recipient's Unique Entity Identifier**

**31. Assistance Type**

Project Grant

**32. Type of Award**

Service

**33. Approved Budget**

(Excludes Direct Assistance)

I. Financial Assistance from the Federal Awarding Agency Only

II. Total project costs including grant funds and all other financial participation

a. Salaries and Wages	\$6,896,154.00
b. Fringe Benefits	\$3,103,269.00
c. Total Personnel Costs	\$9,999,423.00
d. Equipment	\$0.00
e. Supplies	\$0.00
f. Travel	\$232,000.00
g. Construction	\$0.00
h. Other	\$0.00
i. Contractual	\$2,424,950.00
j. TOTAL DIRECT COSTS	\$12,656,373.00
k. INDIRECT COSTS	\$250,000.00
l. TOTAL APPROVED BUDGET	\$12,906,373.00
m. Federal Share	\$7,108,750.00
n. Non-Federal Share	\$5,797,623.00

**34. Accounting Classification Codes**

FY-ACCOUNT NO.	DOCUMENT NO.	ADMINISTRATIVE CODE	OBJECT CLASS	AMT ACTION FINANCIAL ASSISTANCE	APPROPRIATION
2-3984521	FPHPA6553A	FPH70	41.51	\$7,108,750.00	75-22-0359





# DEPARTMENT OF HEALTH AND HUMAN SERVICES Notice of Award

Office of the Secretary

Award# 1 FPHPA006553-01-00

FAIN# FPHPA006553

Federal Award Date: 03/24/2022

## Remarks (Continuation)

This Notice of Award provides funding below the total amount requested in the application for the budget period. OASH is not obligated to make additional Federal Funds available. All award decisions, including the level of funding, are final and you may not appeal. You should re-submit an SF 424A and Budget Narrative justification which includes the total cumulative cost for each cost for the budget reimbursement period based on Personnel, Fringe, Travel, Supplies, Contractual, Other and Indirect cost by object class categories. The budget should be resubmitted for the total awarded amount within 30 days of the start of the budget period on this Notice of Award. Prior approval of the revised budget by the Grants Management Officer is required. Changes in scope proposed as part of the budget revision should be clearly noted and also require Grants Management Officer prior approval.



### 35. Terms And Conditions

#### SPECIAL TERMS AND REQUIREMENTS

1. **Program Income Use.** Program income (fees, premiums, third-party reimbursements which the project may reasonably expect to receive), as well as State, local and other operational funding, will be used to finance the non-federal share of the scope of project as defined in the approved grant application and reflected in the approved budget. Program income and the level projected in the approved budget will be used to further program objectives. Box 28 on this Notice of Award (NoA) indicates **Other**. Program Income may be used to meet the cost sharing or matching requirement of the Federal award. The amount of the Federal award stays the same. Program Income in excess of any amounts specified must be added to the Federal funds awarded. They must be used for the purposes and conditions of this award for the duration of the Project period. 45 C.F.R. § 75.307 (e).

2. **Program Specific Regulation.** In accepting this award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of 42 CFR Part 59, Subpart A.

3. **OPA Program Priorities.** All recipients must comply with the requirements regarding the provision of family planning services that can be found in the statute (Title X of the Public Health Service Act, 42 U.S.C. § 300 et seq.) and the implementing regulations (42 C.F.R. Part 59, Subpart A), and any legislative mandates. In addition, sterilization of clients as part of the Title X program must be consistent with 42 C.F.R. Part 50, Subpart B ("Sterilization of Persons in Federally Assisted Family Planning Projects").

In addition to the statute, regulations, legislative mandates, and additional program guidance that apply to Title X, OPA establishes program priorities that represent overarching goals for the Title X program. OPA expects recipients to develop and implement plans to address program priorities. The current priorities are: 1) advance health equity through the delivery of Title X services; 2) improve and expand access to Title X services; and 3) deliver Title X services of the highest quality.

4. **Notice of Change in Service Sites.** In order to maintain an accurate record of current Title X service sites, grantees must provide notice to the Office of Population Affairs (OPA) of any deletions, additions, or changes to the name, location, street address and email, services provided on-site, and contact information for Title X grantees and service sites. This database will also be used to verify eligibility for 340B program registration and recertification. You must enter your changes to the Title X database within 30 days from the official approval of the change at <https://opa-fpclinicdb.hhs.gov/>. This does not replace the prior approval requirement under HHS grants policy for changes in project scope, including clinic closures.

5. **340B Program Participation.** If you or your sub-recipient(s) enrolls in the 340B Program, you must comply with all 340B Program requirements. You may be subject to audit at any time regarding 340B Program compliance. 340B Program requirements are available at <https://www.hrsa.gov/opa/program-requirements/index.html>.

6. **FPAR reporting.** For each calendar year covered by the project period, you will be required to submit a Family Planning Annual Report (FPAR). The information collection (reporting requirements) and format for this report have been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0990-0479 (Expires 9/30/2024). The FPAR data elements, instrument, and instructions are found on the OPA Web site at <http://opa.hhs.gov>. You are expected to use the FPAR data to inform your QI/QA activities.

7. **Evaluation Cooperation.** The grantee is expected to participate in OPA research and evaluation activities, if selected, and must agree to follow all evaluation protocols established by OPA or its designee.

8. **Grantee Meetings.** The grantee is encouraged to actively participate in all OPA-supported Title X grantee meetings and grantee conferences. In addition to training and technical assistance available from the Reproductive Health National Training Center and the National Clinical Training Center for Family Planning, OPA is planning to conduct two Title X grantee trainings in 2022 and a Title X grantee conference in 2023.



## DEPARTMENT OF HEALTH AND HUMAN SERVICES Notice of Award

Office of the Secretary

Award# 1 FPHPA006553-01-00

FAIN# FPHPA006553

Federal Award Date: 03/24/2022

9. **Institutional Review Board (IRB).** Institutional Review Board (IRB) approvals, when required, must be submitted via Grant Solutions Grant Notes within 5 business days of receipt from the IRB. No activities that require IRB approval may take place prior to your receipt of the IRB approval.
10. **Maximizing Access.** In furtherance of maximizing access and best serving individuals in need in the service areas, recipients should make reasonable efforts to avoid duplication of effort in the provision of services across the Title X network. For example, Title X recipients' coverage areas may overlap geographically, but duplication of subrecipient sites could be minimized or avoided to create more opportunities for services.
11. **Prior Approval for Vehicle Purchases.** No mobile health unit(s) or other vehicle(s), even if proposed in the application for this award, may be purchased with award funds without prior written approval from the grant management officer. Requests for approval of such purchases must include a justification with a cost-benefit analysis comparing both purchase and lease options. Such requests must be submitted as a Budget Revision Amendment in Grant Solutions.

### STANDARD TERMS

1. **Compliance with Terms and Conditions.** You must comply with all terms and conditions outlined in the grant award, including grant policy terms and conditions contained in applicable Department of Health and Human Services (HHS) Grant Policy Statements (GPS), (note any references in the GPS to 45 C.F.R. Part 74 or 92 are now replaced by 45 C.F.R. Part 75, and the SF-269 is now the SF-425), and requirements imposed by program statutes and regulations, Executive Orders, and HHS grant administration regulations, as applicable; as well as any requirements or limitations in any applicable appropriations acts. By drawing or otherwise obtaining funds for the award from the grant payment system or office, you accept the terms and conditions of the award and agree to perform in accordance with the requirements of the award. The HHS Grants Policy Statement is available at: <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf> Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS awards are at 45 C.F.R. Part 75.
2. **Grants Management Officer Prior Approval Requirements.** Certain changes to your project or personnel require prior approval from the Grants Management Officer (GMO). (See Part II, HHS Grants Policy Statement (GPS), any references in the GPS to 45 C.F.R. Part 74 or 92 are now replaced by 45 C.F.R. Part 75). All amendment requests requiring prior approval must be signed by the grantee authorizing official and or PI/PD and submitted through the GrantSolutions Amendment Module. Only responses signed by the GMO are considered valid. If you take action on the basis of responses from other officials or individuals, you do so at your own risk. Such responses will not be considered binding by or upon any OASH Office or HHS component. Any other correspondence not relating to a prior approval item should be uploaded to Grant Notes within the GrantSolutions system. Include the Federal grant number and signature of the authorized business official and the project director on all such correspondence.
3. **Salary Limitation (Further Consolidated Appropriations Act, 2022, Div. H, Title II, sec. 202).** "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II."  
  
The Salary Limitation is based upon the Executive Level II of the Federal Executive Pay Scale. Effective January 2022, the Executive Level II salary is \$203,700. For the purposes of the salary limitation, the direct salary is exclusive of fringe benefits and indirect costs. An individual's direct salary is not constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to the grant or cooperative agreement. A recipient may pay an individual's salary amount in excess of the salary cap with non-federal funds.
4. **Reporting Subawards and Executive Compensation.**



## DEPARTMENT OF HEALTH AND HUMAN SERVICES Notice of Award

Office of the Secretary

Award# 1 FHPA006553-01-00

FAIN# FHPA006553

Federal Award Date: 03/24/2022

### A. Reporting of first-tier subawards.

#### 1) Applicability.

Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates \$30,000 or more in Federal funds that does not include Recovery Act funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

#### 2) Where and when to report.

You must report each obligating action described in paragraph A.1. of this award term to the Federal Funding Accountability and Transparency Act Subaward Reporting System (FFRS). For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

#### 3) What to report.

You must report the information about each obligating action as specified in the submission instructions posted at <http://www.fhrs.gov>.

### B. Reporting Total Compensation of Recipient Executives.

#### 1) Applicability and what to report.

You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if—

a) The total Federal funding authorized to date under this award is \$30,000 or more;

b) In the preceding fiscal year, you received—

(1) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 C.F.R. §170.320 (and subawards); and

(2) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 C.F.R. §170.320 (and subawards); and

c) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at the Executive Compensation page of the SEC website.)

#### 2) Where and when to report.

You must report executive total compensation described in paragraph B.1. of this award term:



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- a) As part of your registration profile in the System for Award Management (SAM).
- b) By the end of the month following the month in which this award is made, and annually thereafter.

### C. Reporting of Total Compensation of Subrecipient Executives.

- 1) Applicability and what to report.

Unless you are exempt as provided in paragraph D of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—

- a) In the subrecipient's preceding fiscal year, the subrecipient received—
  - (1) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 C.F.R. § 170.320 (and subawards); and
  - (2) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
- b) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. § 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at the Executive Compensation page of the SEC website.)

- 2) Where and when to report.

You must report subrecipient executive total compensation described in paragraph C.1. of this award term:

- a) To the recipient.
- b) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

### D. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- 1) Subawards, and
- 2) The total compensation of the five most highly compensated executives of any subrecipient.

### E. Definitions.



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For purposes of this award term:

1) "Entity"

This term means all of the following, as defined in 2 C.F.R. Part 25:

- a) A Governmental organization, which is a State, local government, or Indian tribe;
- b) A foreign public entity;
- c) A domestic or foreign nonprofit organization;
- d) A domestic or foreign for-profit organization;
- e) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

2) "Executive"

This term means officers, managing partners, or any other employees in management positions.

3) "Subaward":

- a) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
- b) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec. II .210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").
- c) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

4) "Subrecipient"

This term means an entity that:

- a) Receives a subaward from you (the recipient) under this award; and
- b) Is accountable to you for the use of the Federal funds provided by the subaward.

5) "Total compensation"

This term means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 C.F.R. § 229.402(c)(2)):

- a) Salary and bonus.



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b) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

c) Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.

d) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

e) Above-market earnings on deferred compensation which is not tax-qualified.

f) Other compensation, if the aggregate value of all such other compensation (e.g. severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

### 5. Intellectual Property and Data Rights.

A. Data. The federal government has the right to: 1) Obtain, reproduce, publish, or otherwise use the data produced under this award; and 2) Authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

B. Copyright. The awardee may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a federal award. The federal government reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

C. Patents and Inventions. The awardee is subject to applicable regulations governing patents and inventions, including government- wide regulations issued by the Department of Commerce at 37 CFR part 401.

6. **Acknowledgement of Federal Grant Support.** When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter "statements")-- describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

- 1) the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
- 2) the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with 100 percent funded by [PROGRAM OFFICE]/OASH/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:





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This [project/publication/program/website, etc.] [is/was] supported by the [full name of the PROGRAM OFFICE] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with XX percentage funded by [PROGRAM OFFICE]/OASH/HHS and \$XX amount and XX percentage funded by non-government source(s). The contents are those of the author (s) and do not necessarily represent the official views of, nor an endorsement, by [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

**Any amendments by the recipient to the acknowledgement statement must be coordinated with the OASH federal project officer and the OASH grants management officer.**

If the recipient plans to issue a press release concerning the outcome of activities supported by this financial assistance, it should notify the OASH federal project officer and the OASH grants management officer in advance to allow for coordination.

7. **Whistleblower Protections.** You are hereby given notice that the 48 C.F.R. § 3.908 (related to the enhancement of contractor employee whistleblower protections), implementing 41 U.S.C. § 4712, as amended (entitled "Enhancement of contractor protection from reprisal for disclosure of certain information") applies to this award.

## 8. Reporting of Matters Related to Recipient Integrity and Performance.

### A. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

### B. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- 1) Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- 2) Reached its final disposition during the most recent five-year period; and
- 3) If one of the following:
  - a) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;
  - b) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;



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c) An administrative proceeding, as defined in paragraph 5 of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or

d) Any other criminal, civil, or administrative proceeding if:

- (1) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
- (2) It had a different disposition arrived at by consent or compromise with an acknowledgement of fault on your part; and
- (3) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

### C. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph B of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

### D. Reporting Frequency

During any period of time when you are subject to this requirement in paragraph A of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

### E. Definitions

For purposes of this award term and condition:

- 1) Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.
- 2) Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- 3) Total value of currently active grants, cooperative agreements, and procurement contracts includes—
  - a) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and



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- b) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

F. Disclosure Requirements.

Consistent with 45 C.F.R. § 75.113, applicants and recipients must disclose, in a timely manner, in writing to the HHS Awarding Agency, with a copy to the HHS Office of the Inspector General, all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in writing to the prime recipient (pass through entity) and the HHS Office of the Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Disclosures must be sent in writing to the awarding agency and to the HHS OIG at the following addresses:

*HHS OASH Grants and Acquisitions Management  
1101 Wootton Parkway, Plaza Level  
Rockville, MD 20852*

AND

*US Department of Health and Human Services Office of Inspector General  
ATTN: OIG HOTLINE OPERATIONS—MANDATORY GRANT DISCLOSURES  
PO Box 23489  
Washington, DC 20026*

URL: <http://oig.hhs.gov/fraud/report-fraud/index.asp>

(Include "Mandatory Grant Disclosures" in subject line)

**Fax:** 1-800-223-8164 (Include "Mandatory Grant Disclosures" in subject line)

Failure to make required disclosures can result in any of the remedies described in 45 C.F.R. § 75.371 ("Remedies for noncompliance"), including suspension or debarment (See also 2 C.F.R. Parts 180 & 376 and 31 U.S.C. § 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

- 9. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.** You must administer your project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

-- You must take reasonable steps to ensure that your project provides meaningful access to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

-- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

-- HHS funded health and education programs must be administered in an environment free of sexual harassment, see



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<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

-- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, *see* <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

10. **Trafficking in Persons.** This award is subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104)

A. Provisions applicable to a recipient that is a private entity.

- 1) You as the recipient, your employees, subrecipients under this award, and subrecipients' employees may not
  - a) Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
  - b) Procure a commercial sex act during the period of time that the award is in effect; or
  - c) Use forced labor in the performance of the award or subawards under the award.
- 2) We as the Federal awarding agency may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity –
  - a) Is determined to have violated a prohibition in paragraph A.1 of this award term; or
  - b) Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph A.1 of this award term through conduct that is either-
    - (1) Associated with performance under this award; or
    - (2) Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 C.F.R. Part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 C.F.R. Part 376.

B. Provision applicable to a recipient other than a private entity.

We as the Federal awarding agency may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity-

- 1) Is determined to have violated an applicable prohibition in paragraph a.1 of this award term; or
- 2) Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1 of this award term through conduct that is either
  - a) Associated with performance under this award; or
  - b) Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an



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organization that are provided in 2 C.F.R. Part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 C.F.R. Part 376.

### C. Provisions applicable to any recipient.

- 1) You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph A.1 of this award term
- 2) Our right to terminate unilaterally that is described in paragraph A.2 or B of this section:
  - a) Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. § 7104(g)), and
  - b) Is in addition to all other remedies for noncompliance that are available to us under this award.
- 3) You must include the requirements of paragraph A.1 of this award term in any subaward you make to a private entity.

### D. Definitions. For purposes of this award term:

- 1) "Employee" means either:
  - a) An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or
  - b) Another person engaged in the performance of the project or program under this award and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements.

#### 2) "Forced labor" means:

Labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.

#### 3) "Private entity":

- a) Means any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 C.F.R. § 175.25.

#### b) Includes:

(1) A nonprofit organization, including any nonprofit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 C.F.R. § 175.25(b).

(2) A for-profit organization.



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4) "Severe forms of trafficking in persons," "commercial sex act," and "coercion"

These terms have the meanings given at section 103 of the TVPA, as amended (22 U.S.C. § 7102)

### 11. Prohibition on certain telecommunications and video surveillance services or equipment.

A. As described in CFR 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

- 1) Procure or obtain,
- 2) Extend or renew a contract to procure or obtain; or
- 3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
  - a) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
  - b) Telecommunications or video surveillance services provided by such entities or using such equipment.
  - c) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

## REPORTING REQUIREMENTS

1. **Financial Reporting Requirement—Federal Financial Report (FFR) SF 425.** Effective October 1, 2020, you must submit your SF-425 to OASH using the Department of Health and Human Services (HHS) Payment Management System for any OASH awards with a project period ending October 1, 2020 or later. Failure to submit the FFR in the correct system by the due date may delay processing of any pending requests or applications.

OASH and the Program Support Center are collaborating in the submission of the SF-425 to reduce the burden on grantees and assist with the reconciliation of expenditures and disbursements, and to allow for timely closeout of grants. Your submission must be through the HHS Payment Management System. SF-425 submissions through Grant Solutions will no longer be accepted for OASH awards.

You must use the SF-425 Federal Financial Report (FFR) for expenditure reporting. To assist in your preparation for submission you may find the SF-425 and instructions for completing the form on the Web at: <http://apply07.grants.gov/apply/forms/sample/SF425-V1.0.pdf>. You must complete **all** sections of the FFR.



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### A. Quarterly FFR Due Date.

Your FFR is due 30 days after the end of each Quarter in the federal fiscal year. That is for the:

**Quarter ending September 30, your FFR is due October 30**

**Quarter ending December 31, your FFR is due January 30**

**Quarter ending March 30, your FFR is due April 30**

**Quarter ending June 30, your FFR is due July 30.**

### B. Final FFR Due Date.

Your final FFR covering the entire project is due 90 days after the end date for your project period.

### C. Past due reports.

If you have not submitted by the due date, you will receive a message indicating the report is **Past Due**. Please ensure your Payment Management System account and contact information are up to date so you receive notifications.

### D. Electronic Submission.

Electronic Submissions are accepted only via the HHS Payment Management System – No other submission methods will be accepted without prior written approval from the GMO. You must be assigned to the grant with authorized access to the FFR reporting Module when submitting. If you encounter any difficulties, contact the HHS Payment Management System Help Desk or your assigned Grants Management Specialist. Please reference the CONTACTS section of NoA Terms and Conditions to locate the name of your assigned Grants Management Specialist.

- 2. Annual Progress Report Requirements.** You must submit annual progress reports 90 days after the end of each performance reporting period unless otherwise required under the Special Terms and Requirements for this award. Your progress reports must address content required by 45 CFR § 75.342(b)(2). Additional progress reporting may be required under Special Terms and Requirements as required by statute, regulation, or specific circumstances warranting additional monitoring. Additional guidance may be provided by the Program Office. Reports must be submitted electronically via upload to Grant Notes in GrantSolutions.
- 3. Audit Requirements.** The Single Audit Act Amendments of 1996 (31 U.S.C. §§ 7501-7507) combined the audit requirements for all entities under one Act. An audit is required for all non-Federal entities expending Federal awards, and must be consistent with the standards set out at 45 CFR Part 75, Subpart F ("Audit Requirements"). The audits are due within 30 days of receipt from the auditor or within 9 months of the end of the fiscal year, whichever occurs first. The audit report when completed should be submitted online to the Federal Audit Clearinghouse at <https://harvester.census.gov/facides/Account/Login.aspx>.

## CONTACTS

- 1. Fraud, Waste, and Abuse.** The HHS Inspector General accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in Department of Health and Human Services' programs. Your information will be reviewed promptly by a professional staff member. Due to the high volume of information that they receive, they are unable to reply to submissions. You may reach the OIG through various channels.





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Internet: <https://forms.oig.hhs.gov/hotlineoperations/index.aspx>

Phone: 1-800-HHS-TIPS (1-800-447-8477)

Mail: US Department of Health and Human Services

Office of Inspector General

ATTN: OIG HOTLINE OPERATIONS

PO Box 23489

Washington, DC 20026

For additional information visit <https://oig.hhs.gov/fraud/report-fraud/index.asp>

2. **Payment Procedures.** Payments for grants awarded by OASH Program Offices are made through Payment Management Services (previously known as the Division of Payment Management) <https://pms.psc.gov/home.html>. PMS is administered by the Program Support Center (PSC), HHS. NOTE: Please contact the Payment Management Services to establish an account if you do not have one.

Inquiries regarding payments should be directed to <https://pms.psc.gov/home.html>; or

Payment Management Services, P.O. Box 6021, Rockville, MD 20852;

or 1-877-614-5533.

3. **Use of Grant Solutions.** GrantSolutions is our web-based system that will be used to manage your grant throughout its life cycle. Please contact GrantSolutions User Support to establish an account if you do not have one. Your Grants Management Specialist has the ability to create a GrantSolutions account for the Grantee Authorized Official and Principle Investigator/Program Director roles. Financial Officer accounts may only be established by GrantSolutions staff. All account requests must be signed by the prospective user and their supervisor or other authorized organization official.

For assistance on GrantSolutions issues please contact: GrantSolutions User Support at 202-401-5282 or 866-577-0771, email [help@grantsolutions.gov](mailto:help@grantsolutions.gov), Monday – Friday, 8 a.m. – 6 p.m. ET. Frequently Asked Questions and answers are available at <https://grantsolutions.secure.force.com/>.

4. **Grants Administration Assistance.** For assistance on **grants administration** issues please contact: Robin Fuller, Grants Management Specialist, at (240) 453-8830, or e-mail [robin.fuller@hhs.gov](mailto:robin.fuller@hhs.gov) or mail:

*OASH Grants and Acquisitions Management Division*

*Department of Health and Human Services*

*Office of the Secretary*

*Office of the Assistant Secretary for Health*

*1101 Wootton Parkway, Rockville, MD 20852.*